Self-Management Education
in
Pulmonary Rehabilitation
for
Patients with COPD

by

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ABSTRACT

Pulmonary rehabilitation (PR) is an effective strategy to manage chronic obstructive pulmonary disease (COPD). Self-management is an evolving and under-researched area within PR. The aim of this thesis was to explore the impact of self-management on health outcomes in patients with COPD.

Methods and Results

The thesis was comprised of four studies. In a survey, all 27 PR programmes in North West England included self-management education, but there were differences in who delivered this component and the content and delivery formats. An interrogation of a clinical database to explore the relationship between COPD self-management, measured using the Bristol COPD Knowledge Questionnaire (BCKQ), with functional capacity, respiratory disability and emotional functioning demonstrated an improvement post PR intervention in all measures but there was no relationship found between the BCKQ and the other health outcomes, in 825 COPD patients attending one PR programme. This raised the possibility about the appropriateness of the self-management strategy in this PR service and the relevance of the self-management measure used. A literature review using systematic methods identified 13 randomised controlled trials investigating the impact of self-management in COPD (none in PR). The self-management strategies used were consistent with the PR service in the above study but suggested that other measures might be more appropriate to estimate self-management. Therefore, 266 patients were asked to complete the BCKQ, Understanding COPD (UCOPD) questionnaire and the Chronic Disease Self-Efficacy (CDSES) questionnaire at the start and end of PR. This showed all measures of self-management improved with PR self-management intervention (BCKQ 27.7%, UCOPD 45.2%, CDSES 30.9%), there was a relationship between the UCOPD and CDSES but except for emotion and the CDSES, there was no relationship between the UCOPD and CDSES and the other clinical measures post intervention.

Conclusion

The findings confirm that there is a lack of a supporting evidence base to inform guidelines for clinical practice on self-management in PR, particularly how to optimise health outcomes through self-management strategies. Further research is needed on which measures of self-management are appropriate for evaluating this component of PR.

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ABBREVIATIONS

ADL	Activities of Daily Living
ATS	American Thoracic Society
BCKQ	Bristol COPD Knowledge Questionnaire
BLF	British Lung Foundation
BP	Blood Pressure
BTS	British Thoracic Society
COPD	Chronic Obstructive Pulmonary Disease
CSP	Chartered Society of Physiotherapists
DNA	Did Not Attend
DNWTA	Did Not Want to Attend
DoH	Department of Health
ERS	European Respiratory Society
FEV1	Forced Expiratory Volume in 1 second
GOLD	Global Initiative for COPD
GP	General Practitioner
HADS	Hospital Anxiety and Depression Scale
HR	Heart Rate
HRQoL	Health Related Quality-of-life
ISWT	Incremental Shuttle Walk Test
LCCG	Liverpool Clinical Commissioning Group
LHCH	Liverpool Heart and Chest NHS Hospital Foundation Trust
LINQ	Lung Information Needs Questionnaire
LPCT	Liverpool Primary Care Trust
LVF	Left Ventricular Failure
MRC	Medical Research Council
NHS	National Health Service
NICE	National Institute for Clinical Excellence
PCT	Primary Care Trust
PR	Pulmonary Rehabilitation
RCT(s)	Randomised Controlled Trial(s)
SD	Standard Deviation
SGRQ	St George's Respiratory Questionnaire
SWT	Shuttle Walk Test
UCLAN	University of Central Lancashire
UCOPD	Understanding COPD
WHO	World Health Organisation
6MWT	Six Minute Walk Test

CHAPTER ONE
THESIS INTRODUCTION

In this section, the research student will set the scene for this thesis. Firstly, there are some reflections on the personal circumstances and reasons for undertaking the research and an overview of the research journey to set some context. Then there is an outline of issues relating to Chronic Obstructive Pulmonary Disease (COPD), its management and Pulmonary Rehabilitation (PR) to set the research context.

1.1 SETTING THE PERSONAL SCENE

"Human behaviour flows from three main sources: desire, emotion and Knowledge"
Plato (Greek philosopher), 424/423 BC–348/347 BC

This thesis is the chronicle of a personal journey of learning, self-discovery, knowledge and skills attainment. The seed was sown in 2007 when I had a change in my clinical role and became Clinical Lead for Chest Medicine and Pulmonary Rehabilitation (PR) at the Liverpool Heart and Chest Hospital. As an experienced clinical specialist physiotherapist in Chest Medicine with a specialist interest in multiple pathology management, it was impossible not to be compelled by the levels of anxiety, depression, distress and disability observed among patients with COPD attending the PR programme. The overwhelming impact of their disease on their quality-of-life, was especially pronounced among the most distressed patients, who often appeared to have very poor knowledge or insight into their condition. This visceral response to the patients' plight suggested to me that a review and remodelling of the PR programme, and its delivery, was needed. The PR programme needed to be able to meet the complex and diverse needs of each patient referred for PR, in order to make a tangible difference to the quality of care being delivered and patients' ability to manage their condition better post PR.

In my new role, I was able to action service remodelling following a joint needs analysis of local population data. This needs analysis showed that there was a need for the educational aspect of the PR service to truly incorporate self-management skills to address practical issues such as medication adherence, inhaler technique and symptom control, especially when the patient was unwell or experiencing a flare up of respiratory symptoms (exacerbation). This need was evident through the high levels of healthcare resource utilisation, high COPD related hospital admissions and readmission rates

observed locally. The service remodelling was carried out in conjunction with the Liverpool Primary Care Trust commissioners. It led to changes to the service level agreement between the NHS Trust and the commissioners as well as an in-house review of clinical guidelines for PR.

Through undertaking the service remodelling, it very quickly became apparent to me that not only was there a lack of available research or guidance for clinicians like myself to support the process of understanding self-management within this patient group, but also that the characteristics of the Liverpool PR patient cohort was poorly understood. This was especially true with regards to the self-management aspect of the rehabilitative process. Last, but certainly not least, I realised that I also had a lack of research skills to understand the remit of the work required to maximise the potential of the service to meet patients' needs. The timing of these redevelopments coincided with a period during which the scope for further professional development seemed limited due to the highly specialist nature of the Clinical Lead role. This served as part of the motivation to apply for a North West NHS Strategic Health Authority (SHA) funded PhD studentship, an opportunity that occurred during this time. The opportunity to choose the area of research was an added attraction of the PhD studentship as it afforded the chance to pursue an understanding of the phenomenon of self-management within the patient population.

Journey of Discovery

This thesis plots my personal journey as a clinician and novice researcher on what has been a real voyage of discovery. This thesis also charts the evolution of my understanding of what the concept of self-management is and what it could mean for patients with COPD, as well as, what it should mean for clinicians and researchers alike. When the journey started out, my knowledge of self-management in COPD had been derived from my discussions with the commissioners. Through the service level agreement, it was agreed that we would deliver a patient self-management programme in parallel with the exercise programme and that the outcome of this should be measured using the Bristol COPD Knowledge Questionnaire (BCKQ). The commissioner led decision to use the BCKQ as a knowledge based measure of self-management was made because it was consistent with the theory of self-management of the period. This was that self-management was formalised patient education aimed at teaching skills needed to carry out medical regimens specific to the disease, guide health behaviour change and provide emotional support for patients to control their disease and live functional lives (Bourbeau, 2003).

Programme Overview

At the time of starting the PhD in 2010, I started a search of the literature for evidence to support the use of self-management education in PR. I discovered that there was no standardised format to PR in the United Kingdom (UK), so as part of my PhD I have carried out a survey of PR services in the region to ascertain how other services managed this aspect of care. Following that, I undertook a retrospective analysis of data routinely collected by the Liverpool Heart and Chest Hospital to support monitoring of health outcomes for reporting to commissioners. This data was stored on a 'PR database'. This study explored how health outcomes responded to PR self-management education. The findings raised questions about the efficacy of the PR intervention to effect change and the suitability of the BCKQ to measure self-management. Therefore, a literature review using systematic methodology to identify how self-management has been delivered in trials of effectiveness and ways of measuring its impact was carried out. The literature review established that the Liverpool self-management education strategy was coherent with those strategies used in published studies and it helped to source appropriate measures of self-management. These measures were used in a prospective analysis of health outcomes in a cohort of PR patients to further explore the concept of self-management within the Liverpool PR cohort and to contribute to the body of evidence about self-management for COPD.

Over the period of this programme of study, my understanding of the concept of self-management has evolved from a knowledge governed, uni-dimensional process, to a holistic and multi-dimensional concept, which is proactive, preventative and responsive to the individual patient's needs. This holistic concept of self-management is described by Young et al. (2015) as "the systematic provision of supportive interventions designed to increase patients' skills in decision-making, problem-solving, utilising resources and taking action''. This programme of study has also enabled me to gain knowledge and an increased understanding of research and research methods. As a direct result of this increased knowledge and understanding, I have been able to develop practical research skills such as literature searching, study design, data collection and data analysis. In addition, I have developed an understanding of the process by which clinical research can be used to inform the development, design, evaluation and implementation of effective clinical interventions.

1.2 BACKGROUND

1.2.1 Chronic Obstructive Pulmonary Disease

Chronic Obstructive Pulmonary Disease (COPD) is an umbrella term used for a number of chronic lung disorders characterised by airflow obstruction due to a combination of airway and parenchymal damage (NICE, 2004; NICE, 2010). COPD is a preventable and treatable condition, which is characterised by frequent dyspnoea and an increased inflammatory response in both the airways and the lungs when patients are exposed to damaging gases and or particles (Global Initiative for Chronic Obstructive Lung Disease - GOLD, 2016).

The primary symptom of COPD, dyspnoea, has been reported in 94% of COPD patients (Blinderman et al., 2009) and is characterised by persistent airflow limitation (Abramson et al., 2014), hyperinflation, abnormal gas exchange, mucus hypersecretion, pulmonary hypertension, exacerbations (flare up or worsening of symptoms) and other systemic issues, such as, cardiac issues (Cannon et al., 2016). These symptoms of COPD decrease patients' sense of control, increase their levels of anxiety and depression, and, in addition, reduce their confidence and ability to perform activities of daily living, all of which greatly impact on quality-of-life (Abramson et al., 2015).

In COPD, the airflow obstruction is usually progressive, not fully reversible and does not change markedly over several months. The National Institute for Clinical Excellence (2010) recommends that clinicians consider a diagnosis of COPD and perform spirometry if COPD seems likely in patients who are:

- Over 35 years old
- Have any of these symptoms:
  - exertional breathlessness
  - chronic cough
  - regular sputum production
  - frequent winter 'bronchitis'
  - wheeze
- and have no clinical features of asthma

1.2.2 Epidemiology of COPD

Historically, three major risk factors were identified for COPD, namely, cigarette smoking, heavy exposure to occupational and indoor air pollution and α1-antitrypsin deficiency, a recessive genetic trait common in individuals from Northern Europe and virtually absent from other populations (Lopez et al., 2006). In contemporary populations, the disease is

predominantly caused by smoking (NICE, 2004; NICE, 2010) and accounts for 80 – 90% of COPD risk in developed countries (Lopez et al., 2006). Other factors such as exposure to airborne pollution and exposure to harmful fumes or particles at home or at work (British Lung Foundation, 2010) are now less common causes. Epidemiological studies by the American Thoracic Society (2003), Blanc and Toren (2007) and the Health and Safety Executive (HSE, 2016) estimate that 15% of COPD is occupation-related. More recently, GOLD (2016) stated that the risk factors for the development of COPD involves a gene-environment interaction. α1-antitrypsin deficiency and the gene encoding matrix Metalloproteinaise 12 (MMP12) have been identified as contributing to declines in lung function. The environmental factors include age, gender, lung growth, lung development, socio-economic status, asthma, bronchial hyperactivity, chronic bronchitis, infections, exposure to particles such as cigarette smoke, occupational chemicals and dust.

COPD is the only major cause of death in which the incidence is on the increase (Murray and Lopez, 1997): an estimated 1.5 million people in the United Kingdom were identified as being affected by COPD at the beginning of the millennium (NICE, 2004) and by 2010, this estimate had risen to 3 million people (NICE, 2010; Chatwin et al., 2016). The incidence of COPD is equivalent to 13% of the population of England aged 35 and over (Department of Health, 2010). Worldwide, COPD is the fourth leading cause of death and is one of the leading causes of hospitalisation and associated health costs (Gershon et al., 2011). The European Respiratory Society (2003) predict that COPD is expected to be the third leading cause of death worldwide by 2020.

In the UK, COPD is the second commonest cause of hospitalisation (Chatwin et al., 2016). COPD accounts for a substantial number of deaths in Great Britain with between 25,000 and 30,000 deaths each year over the last 25 years in England and Wales (National Statistics, 2008; HSE, 2016). Up to 4,000 deaths may be attributed to workplace-related exposure to dust particles (including, coal, grain, and silica) and fumes and chemicals (including welding fumes, isocyanates, and polycyclic aromatic hydrocarbons) (HSE, 2016). National figures showed that COPD accounted for 4.8% of all deaths in England between 2007 and 2009 (National End of Life Care Intelligence Network, 2011). Data from the World Health Organisation (WHO) shows that premature mortality from COPD was almost twice as high in the UK as in the rest of Europe and, although premature mortality for COPD has decreased in the last few decades in parallel with the European average for both men and women, the gap between the UK and the European average has not changed (WHO, 2011).

COPD is rare in people under 40 years of age, the prevalence increases with age and it affects 9% of those aged >70 (Snell et al., 2016). COPD rates are highest in lower socioeconomic groups with disease prevalence and incidence being over twice as great in the most deprived population quintile than in the least deprived quintile (Snell et al., 2016). Almost half of all cases occur in those employed in unskilled manual occupations, with the rates in men being around 14 times higher than those in professional roles (Department of Health, 2010). Smoking is more common in these groups: 26% of routine and manual workers smoke compared with 15% of those in managerial and professional occupations (Office for National Statistics, 2007). COPD prevalence, incidence and mortality rates are highest in Scotland and the north of England (Snell et al., 2016); the distribution of COPD in England mirrors the distribution of highly industrial, construction or manual labour areas, such as, Merseyside, Manchester and Lancashire (ONS, 2001). This is unsurprisingly consistent with increased exposure to harmful particles, which increase the risk of COPD in these areas (HSE, 2016) - see Figure 1.1.

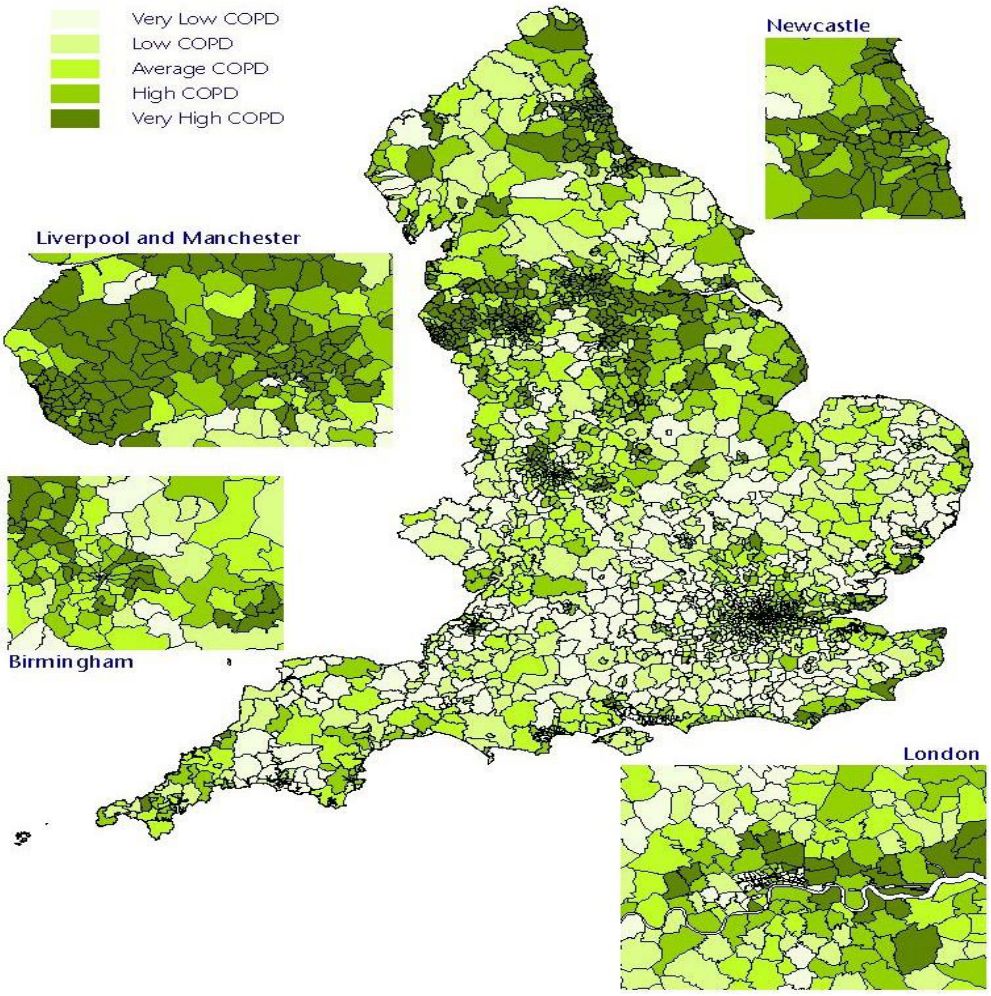

Figure 1.1 - Distribution of COPD in postcode districts in England (ONS Data sources: Hospital Episode Statistics; 2001 Census)

1.2.3 Economic Impact of COPD

In a report evaluating the impact of COPD, the Department of Health estimated that COPD accounts for 1.4 million General Practice (GP) consultations, one million in-patient bed days every year and more than £800 million in direct healthcare costs each year (Department of Health, 2005). In addition to healthcare-related cost, Britton (2003) found that 24% of COPD patients of working age reported that their condition prevented them from working and a further 9% were limited in their ability to work. These findings are substantiated by Department of Health data that shows COPD accounts for 24 million lost working days per annum (Department of Health, 2005). More recent statistics from Snell et al. (2016) reports that COPD accounts for over 140,000 hospital admissions and over a million bed days each year across the UK (1.7% of all hospital admissions and bed days), with 97% of these admissions being for emergency care.

1.2.4 COPD Policy

According to Hansell et al. (2014), between 1985 and 2009, the highest risk of COPD mortality was found in the industrial conurbation areas in the North East, Merseyside and Greater Manchester. Age and deprivation adjusted mortality rates were also highest in the North West of England with male COPD mortality being 69 deaths per 100,000 per year in the North West compared to 53 deaths per 100,000 per year in the South West of England, the lowest in England. Female COPD mortality was reported as approximately two-thirds of male COPD mortality with North West COPD mortality being 50 deaths per 100,000 per year compared to 31 deaths per 100,000 in the South West.

The national COPD audit by the Royal College of Physicians (RCP) and the British Thoracic Society (BTS) in 2003 made several recommendations to reduce the worryingly high and widely varying mortality rates for COPD patients (RCP and BTS, 2004). These included improved access to specialist staff, patient education on their condition, improving COPD treatment and a focus on COPD prevention, which was mainly through smoking cessation (Price et al., 2006). In addition to these recommendations, the National Institute for Clinical Excellence (NICE) recommended diagnostic, treatment and end-of-life management strategies for patients with COPD, which included PR as a core part of optimising patient management (NICE, 2004; Harris et al., 2008; Simpson and Jones, 2013).

The National Service Framework for COPD (Department of Health, 2008) was subsequently developed to:

- provide more patient choice
- reduce inequalities in COPD care
- reduce healthcare utilisation costs
- ensure that all people involved in caring for COPD patients (GP staff, hospital staff, social services) work together to help the patient
- provide a patient focused pathway mapping how services for people with COPD are currently delivered and how this might be improved from stakeholders' perspectives
- outcome measures for monitoring and measuring progress towards and achievement of the quality requirements.

There is a growing body of evidence regarding the effects of PR on the economic impact of COPD. PR is thought to reduce the economic burden on health services by producing safe, practical and cost-effective clinical benefits in those who complete the programme (Ries et al., 2005; Cannon et al., 2016) which may help reduce hospital admissions (Cannon et al., 2016), therefore reducing direct healthcare costs. When considering the cost efficacy of health interventions for COPD patients, Griffiths et al. (2001) found that PR is likely to result in financial benefits to the NHS. According to the National Clinical Strategy for COPD (Department of Health, 2010), widespread use of PR would bring annual savings of around £5.5 million a year. This has been translated into Primary Care Trusts commissioning prioritising the optimisation of COPD care for patients and commissioning PR services to be delivered in collaboration with existing traditional hospital based or primary care based COPD management strategies.

1.3 PULMONARY REHABILITATION

1.3.1 History of Pulmonary Rehabilitation

The exact origin of PR has not been clearly documented in the available literature, therefore it is difficult to establish an exact start date or period for PR. However, up until the middle of the 20th century, medical papers and journals advocated that patients with dyspnoea and other respiratory symptoms avoid activity in order to avoid the breathlessness that activity causes. One of the earliest documentations of a form of rehabilitation in breathless patients was by Barach et al. (1952) who described the achievement of a training effect on two oxygen dependent patients with pulmonary emphysema (now classed as COPD) to the extent that they demonstrated improvement

in exercise capacity without oxygen. Over a decade later, further observations of patients with chronic airway obstruction by Noehren et al. (1964) resulted in the first documented clinical recommendation for symptomatic patients to exercise in order to maintain cardiovascular efficiency, which would in turn result in the restoration of physical fitness. It appears that these initial documentations may have introduced the concept of exercising patients with chronic lung disease as part of a rehabilitative or restorative process.

Subsequent to this, the next documented stage of the evolution of PR seems to have originated in the late 1960s, with the first record of a multi-disciplinary team responsible for the rehabilitation of pulmonary patients (Petty et al., 1969). Petty et al. (1969) described how their team developed a standardised out-patient PR programme, which included the use of supplementary oxygen and instruction for patients on a variety of topics including bronchial hygiene, breathing retraining, physical reconditioning and individualised pharmacologic therapy. They reported improvements in terms of exercise tolerance, reduced hospitalisation and return to gainful employment in 94 out of their first 124 patients.

According to a historical outline of PR by Casaburi (2008), by 1974 Petty's model had begun to be established in clinical practice and may have influenced the American College of Chest Physicians in the development of its definition of PR. In its 1981 statement, the American College of Chest Physicians defined PR as, "an art of medical science wherein an individually tailored multidisciplinary programme is formulated which, through accurate diagnosis, therapy, emotional support and education, stabilises or reverses both the physiology and psycho-pathology of pulmonary disease and attempts to restore the patient to the highest possible function level allowed by his pulmonary handicap and over-all life situation" (American Thoracic Society, 1981). Over time, this definition of PR has evolved to incorporate psychosocial support through family involvement, peer support and the concept of attaining and achieving independence (Cole and Fishman, 1994). More recently, the concepts of holistic therapy, integrated care and self-management, have been added to the definition of PR (Chartered Society of Physiotherapists, 2003).

1.3.2 Aims of Pulmonary Rehabilitation

The primary aim of PR is to reduce disability and handicap in people with lung disease and to improve their quality-of-life while diminishing the health care burden (British Thoracic Society, 2001; Bolton et al., 2013) and instilling lifestyle change (CSP, 2003;

NICE, 2004; Evans and Morgan, 2007; NICE, 2010; Spruit et al., 2013; Vogelmeier, 2017). This method of instilling lifestyle change was aimed at addressing the reversible but physically debilitating aspects of COPD: patients with COPD often decrease their physical activity because exercise can worsen dyspnoea (Cicutto et al., 2004; Simpson and Rocker, 2008; Disler et al., 2012; Cannon et al., 2016). The progressive deconditioning associated with inactivity initiates a vicious cycle with dyspnoea becoming problematic at ever lower physical demands. PR aims to break this vicious cycle using a variety of therapeutic interventions based on exercise and education specifically targeted to address patient symptoms (CSP, 2003; Bolton et al., 2013).

Benefits of PR are thought to include decreased dyspnoea, improved health related quality-of-life, fewer days of hospitalisation and decreased health care utilisation (Ries et al., 2007 and Puhan et al., 2009; Bolton et al., 2013; Vogelmeier et al., 2017). In addition to exercise and education, psychological and behavioural intervention is recommended, as part of PR, to achieve vital gains or improvement in the emotional components of COPD patients' health status, namely, anxiety and depression (Withers et al., 1999).

The Chartered Society of Physiotherapists (CSP) detailed the specifics of this by outlining the aims for PR as:

- to increase exercise tolerance and reduce dyspnoea
- to increase muscle strength and endurance (peripheral and respiratory)
- to improve health related quality-of-life
- to increase independence in daily functioning
- to increase knowledge of lung condition and promote self-management
- to promote long term commitment to exercise (Chartered Society of Physiotherapists, 2003).

Although impairment of lung function does not necessarily reverse with rehabilitation, its measurement or categorisation is useful for the purposes of describing the population expected to benefit from PR. The MRC (Medical Research Council) classification is often used to grade the severity of functional impairment due to patients' dyspnoea or breathlessness related symptoms (Bestall et al., 1999). COPD patients with an MRC dyspnoea scale score of three and above, that is those report being functionally limited by dyspnoea, are thought to benefit more from PR as they tend to be symptomatic by that stage (British Thoracic Society, 2001; NICE, 2004; NICE, 2010).

The British Thoracic Society recommends that the individual assessment of patients and evaluation of programmes should be embedded in the process of the rehabilitation programme (British Thoracic Society, 2001; Bolton et al., 2013). In addition, they recommend that outcome measures of functional capacity and health status are used to evaluate and monitor response to intervention before and after the programme, given that these are the aspects of the patient's condition that the programme aims to improve (British Thoracic Society, 2001; Chartered Society of Physiotherapists, 2003; NICE, 2004; NICE, 2010; Bolton et al., 2013) as those outcome measures are capable of improvement with specifically targeted intervention.

1.3.3 Components of Pulmonary Rehabilitation

In 2004, NICE (2004) defined PR as an MDT programme of care for patients with chronic respiratory impairment, individually tailored, and designed to optimise the individual's physical and social performance and autonomy. According to NICE, PR entails physical training, disease education, nutritional, psychological and behavioural intervention (NICE, 2004).

More recently, the American Thoracic Society's latest statement on PR, in conjunction with the European Respiratory Society, defined it as, "a comprehensive intervention based on a thorough patient assessment followed by patient tailored therapies that include, but are not limited to, exercise training, education and behaviour change designed to improve the physical and psychological condition of people with chronic respiratory disease and to promote the long-term adherence to health enhancing behaviours" (Spruit et al., 2013). According to the most recent Cochrane review of PR for COPD by McCarthy et al. (2015), PR programmes include exercise as a key component; some programmes contain other interventions, such as, assessment, education, psychological support and dietary advice (ATS, 1999; GOLD, 2014; Spruit et al., 2013; McCarthy et al., 2015). However, McCarthy et al. (2015) make it clear that the exercise component of PR increases inspiratory volume and reduces dynamic hyperinflation, both of which reduce dyspnoea during physical activity (Casaburi, 2009). Exercise also increases muscle function, delaying fatigue, and results in increased exercise tolerance. Although less emphasis is placed on the educational component of PR, Spruit (2013) and McCarthy et al. (2015) suggest that the PR educational component focuses on collaborative self-management and behaviour change.

Depending on culture, healthcare systems and resources, the structure, personnel, content and settings of PR programmes may vary (Nici 2006; Spruit, 2013). PR is

typically delivered to groups of patients but there is no evidence to suggest the optimal size of the group (McCarthy et al., 2015). The setting for PR programmes varies with community-based programmes (Wijkstra, 1994; Cambach, 1997; Casey, 2013), home-based PR (Maltais, 2008; Viera, 2010) and hospital based programmes being available (Bourbeau, 2010). The optimal duration of programmes, number of sessions offered per week and type of staff required to deliver PR programmes are unclear (McCarthy et al., 2015). Beauchamp (2011) concluded that the available evidence was insufficient to show the optimal duration of PR for people with COPD. However, they recommended a duration of at least eight weeks to attain a substantial effect.

1.3.4 Evidence for the Effectiveness of Pulmonary Rehabilitation

There is now overriding evidence on the effectiveness of PR as a management strategy for patients with COPD. Multiple studies have demonstrated that PR increases exercise tolerance, improves muscle function, reduces dyspnoea during physical activity and reduces healthcare utilisation (Casaburi and ZuWallack, 2009; Spruit et al., 2013; McCarthy et al., 2015; Volgelmeier et al., 2017). The evidence of the effectiveness of PR has led to the benefits of PR being recognised in clinical guidelines, which advocate the use of PR as an important component in the management of COPD: Guidelines from NICE (2004, 2010), the joint European Respiratory Society (ERS) and American Thoracic Society (ATS) clinical guidelines on the diagnosis and management of stable COPD (Quaseem et al., 2011, the British Thoracic Society guideline on PR in adults (Bolton et al., 2013) and most recently the joint ERS and ATS guidelines for the prevention of exacerbations (Wedzicha et al., 2017) all stipulate the use of PR as part of the routine management of COPD. There is robust research evidence-base to support the rationale for exercise as part of a PR programme: According to Evans and Morgan (2007), PR comprises a programme of activities that must include individually prescribed physical exercise training and self-management education with the aim being to instil a sustained lifestyle change. As part of a Cochrane review of PR for COPD in 2009, the Cochrane Collaboration found that there was no need for additional Randomised Controlled Trials (RCTs) comparing PR and conventional community care in COPD. However, the collaboration remained uncertain of which components of PR are essential, its ideal length, the required degree of supervision and intensity of training, and how long the treatment effect persists (Lacasse et al., 2009). The purpose of this section is to provide a brief overview of the available evidence from the most recent Cochrane review of PR by McCarthy et al. (2015). According to the authors, the objective of this Cochrane review was to compare the effects of PR versus usual care on health-related quality-of-life, functional exercise capacity and maximal exercise capacity in persons with COPD. The

review included any in-patient, out-patient, community-based or home-based rehabilitation programme of at least four weeks' duration that included exercise therapy, with or without any form of education and/or psychological support, delivered to patients with exercise limitation attributed to COPD. The primary outcome was disease-specific health-related quality-of-life and the secondary outcomes were exercise testing using measures of functional exercise capacity and maximal exercise capacity.

A total of 65 studies were reviewed, including 31 RCTs from the 2006 version of the Cochrane review by Lacasse et al. (2006). These studies involved 3822 participants, 2090 of whom were randomly allocated to some form of exercise rehabilitation for a minimum duration of four weeks and 1732 individuals who were randomly assigned to usual care. The sample size in the included studies ranged from 12 participants (Hoff et al., 2007) to 350 participants (Casey et al., 2013) with a median of 45 participants (interquartile range (IQR) 29.5 to 67). We noted a large gender imbalance across all studies, with 69% of participants being male and with 10 studies including no female participants. Only six studies reported patient-based programmes, three of which were combined with a home-based follow-up component. Thirty-seven studies were hospital out-patient based; eight of these included a home-based element. In all, 21 programmes were community-based, 11 of which were entirely home-based, and one programme combined community-based and home-based components. The venue for the programme run by one study (Vijayan et al., 2010) was unclear from the reports. The duration of the programmes ranged from four weeks (three studies) to one year (three studies). Eight-week and 12-week programmes (18 studies of each) were most common. Timelines for assessment of participants followed a pattern identical to that of programme duration.

McCarthy et al. (2015) reported that investigators identified an increase in exercise tolerance and functional activities such as walking as other relevant outcomes of rehabilitation. The authors also reported that PR resulted in greater improvement in health-related quality-of-life and functional exercise capacity when compared with treatment effects of other modalities of COPD care such as long-acting inhaled therapy. The authors found that PR programmes included in the review differed in several aspects including clinical setting, duration and composition, which the authors of the review thought may be responsible for the substantial heterogeneity observed in the results obtained. This is in keeping with recent studies by Spruit et al. (2014) and Rochester et al. (2014) who also identified this as an issue requiring further investigation. One of those areas identified was that the contributions of educational activities and psychological

support to exercise training remained uncertain: McCarthy et al. (2015) reported such information would be of outmost importance to physicians and allied healthcare professionals who prescribe rehabilitation and to those who allocate the resources. However, it was felt that such questions were too specific to be directly addressed in this meta-analysis, which aimed to investigate the overall effect of rehabilitation in COPD, not the effects of its components.

1.3.5 Self-Management Education Intervention in Pulmonary Rehabilitation

Patient education programmes to support patient participation in disease management have been proposed as an important strategy in limiting the growing burden of chronic disease (Lorig and Holman, 2003). In recent years, there has been increased emphasis on the education of patients and their families in medical conditions. This has been driven in part by patients wishing to be better informed about their condition and in part by the recognition by health professionals that self-management is important in order to optimise the effects of clinical intervention (White et al., 2006). In addition, a major catalyst for this change in practice has been the need for health commissioners to reduce the cost of avoidable hospital admissions due to exacerbations with the development and use of admission avoidance schemes in which patient involvement through self-management is key (Bolton et al., 2013).

At the start of this thesis in 2010, the working definition of self-management was any formalised patient education programme aimed at teaching skills needed to carry out medical regimens specific to the disease, guide health behaviour change and provide emotional support for patients to control their disease and live functional lives (Bourbeau, 2003). Healthcare providers play a critical role in helping patients understand the nature of the disease, potential benefits of treatment, addressing concerns regarding potential adverse effects and events, and encouraging patients to develop self-management skills (Bourbeau and Bartlett, 2008).

The earliest self-management programmes included asthma self-management plans that encouraged people to alter their dosages of asthma medication in response to altered symptoms or peak expiratory flow measurements. Whilst early programmes often lacked an explicit theoretical basis, subsequent programmes are based on theoretical models of behaviour such as Bandura's self-efficacy theory (Foster et al., 2009). According to Bandura (1977), the key predictors of successful behaviour change are confidence (self-efficacy) in the ability to carry out an action and the expectation that a particular goal will be achieved. Increasing self-efficacy is seen as a prerequisite for behaviour change to

improve self-management, which in turn may influence health and healthcare use (Foster et al., 2009).

Relating such theories to patient self-management of COPD can be rationalised as follows: COPD causes shortness of breath, which in some cases can be severe. As a result, many individuals with COPD develop a lack of confidence regarding their ability to avoid breathing difficulty while participating in certain activities, however minimal the physical demands of the activity may be. This lack of confidence may be expressed as low self-efficacy. As a result of low self-efficacy, COPD patients may refrain from many routine activities of daily living. Identifying situations in which individuals with COPD experience low self-efficacy would allow the development of specific treatment interventions designed to increase the patient's self-efficacy in these situations and consequently increase activity through improved knowledge, symptom monitoring skills, symptom management skills and action plans for different scenarios the patient may face (Wigal et al., 1991). In turn, the increase in patient activity levels can reverse the debilitating effects of physical deconditioning in COPD, improve confidence and psychomotor functioning, therefore, improving quality-of-life, specifically, health related quality-of-life.

Although improving knowledge is a key component of self-management, it should be used in conjunction with other approaches to facilitate the behavioural change that is required to optimise the management of the patient's condition. Educational interventions for chronic illnesses aim to provide patients with the knowledge and skills to deal with limitations imposed by the disease. Several trials have now been conducted assessing the benefits of educational programmes for the general COPD population. Most studies into stand-alone COPD education included in a Cochrane review of self-management education for COPD demonstrated no benefits (Harris et al., 2008). In terms of PR models, there is little evidence that education can be considered a substitute for exercise training. Four studies by Man et al. (2004), Ries et al. (1995) Toshima et al. (1990) and Wedzicha et al. (1998) in which education alone was compared to treatment with exercise found that education alone was of little benefit.

The original Cochrane review, which aimed to examine self-management in COPD, was published in 2003 and concluded that the effects of self-management programmes were unclear (Monninkhof et al., 2003). However, subsequent Cochrane reviews of self-management education for patients with chronic respiratory disease, published in 2007 and 2009 by Effing et al., concluded that self-management education is associated with

improvement in quality-of-life and a reduction in hospital admissions with no indications of detrimental effects in other outcome parameters (Effing et al., 2007; Effing et al., 2009). However, because of heterogeneity in interventions, study populations, follow-up time, and outcome measures, the findings were insufficient to formulate clear recommendations regarding the form and contents of self-management education programmes in COPD. The resultant recommendation was that clear benchmarks needed to be specified by authoritative bodies about outcome measures and the length of such studies. In addition, future research studies with sufficient sample size and longer follow-up time focusing on the acquisition of self-management skills and behavioural change as well as the definition of the effective elements of self-management programmes were needed. A recent Cochrane review by Zwerink et al. (2014) has confirmed that self-management training improved health related quality-of-life, improved shortness of breath and reduced hospital admissions in COPD patients compared to usual care. However, again due to differences in the types of self-management intervention, authors were unable to draw out key themes or form clear recommendations on the most effective content of self-management training. Most recently, a Cochrane review of self-management interventions by Lenferink et al. (2017) concluded that future studies utilising self-management interventions that meet the requirements of the most recent COPD self-management intervention definition were needed to provide further evidence on this aspect of COPD care.

In reviewing the available evidence on PR, it appears that the evidence on the exercise component of PR has a robust evidence base (McCarthy et al., 2015). But, even this most recent Cochrane review into PR does not include self-management in its scope. It may be that the skeletal body of evidence on this matter and the lack of RCTs to support the rationale for self-management in PR have contributed to the lack of emphasis of self-management in PR for patients with COPD despite the increased emphasis on education of patients and their families generally. Although the evidence suggests that self-management in PR for COPD patients would be beneficial, most of the evidence for self-management in PR comes indirectly from the growing body of evidence to support the effects of self-management programmes in COPD. Further research is needed into its constituents (Zwerink et al., 2014; Lenferink et al., 2017), duration (Zwerink et al., 2014), when to intervene (Effing et al., 2007; Effing et al., 2009; Zwerink et al., 2014), measures of self-management and timing of evaluation (Effing et al., 2007; Effing et al., 2009; Zwerink et al., 2014). Therefore, the implications for research into this aspect of COPD care in PR include the need to identify and replicate particular components of self-management educational programmes, which will lead to improved outcomes. Part of

this process will include the evaluation of overall programmes and research designs should demonstrate how particular components, of the programme and of self-management, contribute to the success or failure of the whole. Such studies should focus on investigating the acquisition of self-management skills, in addition, to just behavioural change.

1.4 SELF-MANAGEMENT THEORY

The evidence makes a strong case that the best type of education for patients experiencing chronic health conditions should include:

1. a disease specific education
2. general managing skills entailing problem solving, finding and using resources appropriately, ability to work in conjunction with the healthcare team
3. use of strategies that that increase patients' confidence (self-efficacy) in their ability to engage in healthy behaviours, i.e., behaviours that are needed to manage their condition on a daily basis
4. adequate peer role models and support networks that help in the initiation and maintenance of the desired behavioural changes.

Traditionally, patient education involving the provision of disease-specific information and teaching specific disease-related skills was recognised as being a vital component of PR (CSP, 2003). Earlier definitions of self-management education were based on the provision of a formalised education programme aimed at teaching patients the skills needed to carry out medical regimens specific to their disease, guide health behaviour change and provide emotional support for patients to control their disease (Bourbeau et al., 2003). The major difference between patient education and self-management education identified by Bodenheimer et al. (2002) is that, traditional patient education provided information and teaching technical disease related skills, whereas self-management education teaches skills on how to act on problems. Although both types of education are useful in assisting patients to achieve better quality of life and independence (Young et al., 2015), there is evidence that traditional patient education is generally not sufficient for people to manage a lifetime of chronic disease care (Gibson et al., 1998; Norris et al., 2002; Krichbaum et al., 2003; Newman et al., 2004; Harris et al., 2008; Wood-Baker et al., 2012). While patients claim to be well informed about coping with COPD, actual knowledge of COPD self-management is limited (Kessler et al., 2006; Stellefson et al., 2012).

Differences between traditional and self-management education can be outlined across five key areas, identifying problems, problem solving, behaviour change, goals and roles as follows (Bodenheimer et al., 2002):

1. **Identifying Problems -** The identification of problems in traditional education relates to identifying widespread common disease related problems, whereas in self-management education, the identification of problems is person specific to the patient and is identified by the patient identifying the problems they wish to be covered.
2. **Problem Solving -** Traditional patient education provides disease specific education and technical skills training in comparison to self-management education where problem solving skills are more generalised to manage the consequences of chronic conditions.
3. **Behavioural Change -** Traditional patient education is based on the underlying theory that disease specific knowledge creates behaviour change, which in turn produces better outcomes, while self-management education, in contrast, is based on the theory that greater patient confidence is his/her capacity to make life improving changes yields better clinical outcomes.
4. **Goals –** traditional education focuses on compliance in contrast to self-management education which is based on increasing patient self-efficacy and improved health outcomes.
5. **Roles –** the health professional is the primary educator in traditional patient education, whereas self-management education enables the role of primary educator t be health professionals, peer leaders or other patients.

Self-management interventions are delivered in a variety of settings and the most popular locations in which health professionals deliver programmes are clinical settings (Barlow et al., 2002). In modern healthcare, a greater emphasis is being placed on healthcare professionals delivering self-management support and using behavioural techniques during routine clinic visits to enhance patients' abilities to be effective self-managers (British Columbia Ministry of Health, 2011). The importance of self-management is clear when it is considered that people with long-term conditions, typically, spend only a few hours each year in contact with health services; for the rest of the time, they are 'self-managing' their condition (Lhussier et al., 2013). Clari et al. (2017) state that despite information and guidelines on self-management, such as, GOLD (2016), individuals with COPD seldom comply with the recommended self-care behaviours and that little is known about what these individuals do to take care of themselves in their daily lives (Lomundal and Steinbekk, 2002; Monninkhof et al., 2004).

The implications of this is often reflected in poorly controlled symptoms, recurrent admissions to hospital for recurrent exacerbations, poor health status and reduced quality of life.

Self-management is recognised as one of the critical components in improving healthcare for people with long-term conditions (Singh, 2005; Tsai et al., 2005; Zwar et al., 2006). Self-management is thought to be pivotal in improving patient activation to act (Hibbard and Gilburt, 2014). Patient activation to act is a vital step in enabling patients in mastering a complex set of self-management behaviours (Spruit et al., 2013). Based on this description, self-management is fundamental to the health and wellbeing of people with long-term conditions. According to Nici et al. (2014), the rationale behind self-management in chronic diseases, such as COPD, is that self-management is considered an integral component of the chronic care model of disease management. In a systematic review by Adams et al. (2007), the chronic care model of disease management was described as including clinical information systems, delivery system redesign, decision support (guidelines), healthcare organisation and community resources (Bodenheimer et al., 2002a). Self-management helps the patient acquire the knowledge and skills required to follow medical therapies and health behaviours changes required to achieve optimal outcomes (Bourbeau and van der Palen, 2009).

The philosophical assumptions underpinning self-management of chronic conditions are that a person with a chronic condition is the expert in managing their life. Although the health professional has expert knowledge about the condition, best health outcomes are achieved when the health professional works in partnership with the person, their family or carers to manage their chronic condition. This indicates that there are individual elements (Lawn et al., 2005), practice elements (Battersby et al., 2010) and system elements (Battersby et al., 2003) involved in the development of self-management. This is consistent with the chronic care model (Wagner et al., 1998), which has been identified as one of the most effective models of chronic disease care paradigms (Johnson et al., 2008). The chronic care model is based on the notion of health professionals collaboratively working with patients, families and carers to acquire the skills and confidence to manage their chronic illnesses, providing self-management tools and routinely assessing problems and accomplishments (Wagner et al., 1998; Johnson et al., 2008). Although the chronic care model is highly clinical in nature and can be used as a framework for providers and healthcare organisations, it has been criticised the lack of a patient's perspective (Barr et al., 2003). An expanded chronic care model, which focused on the patient's perspective by including patients' perception of health promotion

and impact on the community and the health system was subsequently developed by Barr et al. (2003). This productive interaction between the patient and health professionals results in improved health outcomes (Greenhalgh, 2009). Health professionals understanding their role within the chronic care model, requires health professionals to have a better understanding of the available evidence, and for this, further research is required to expand the evidence base for COPD, especially with regards to incorporating self-management education into traditional PR practice. This is consistent with Greenhalgh's ecological model for supported self-management of chronic illness which indicates that an appropriate self-management support from adequately prepared proactive health professionals results in productive interaction with patients with chronic illness, which, in turn results in an informed, active patient, as well as, improved clinical, functional and population health outcomes (Greenhalgh, 2009).

In summary, this overview suggests that self-management is multi-component. When delivered within PR with other components such as exercise, this increases the complexity of the intervention as there likely to be interactions between the different components. It is clear from the evidence-base that self-management has not been adequately evaluated as a component of PR. In the next section, the research student will describe the development phase for a complex intervention and modern approaches to evaluating complex interventions which have helped guide the approach in this thesis.

1.5 DEVELOPING AND EVALUATING COMPLEX INTERVENTIONS

The UK Medical Research Council (MRC) defines a complex intervention as an intervention that comprises multiple interacting components (MRC, 2000). Initial guidelines by the MRC on the development and evaluation of complex interventions recognised the need for different and more pragmatic research designs than standard drug trials but the framework mirrored the standard phases (I to IV) (MRC, 2000). However, the difficulties of implementing complex interventions in practice has led to the realisation that further complexity is added by the multiple levels (e.g. patient, health professional and organisational) involved in the delivery of the intervention, and consequently the concept has evolved and further guidance was published to reflect these differences. (Craig et al., 2008). The framework from these guidelines is shown below (Figure 1.2).

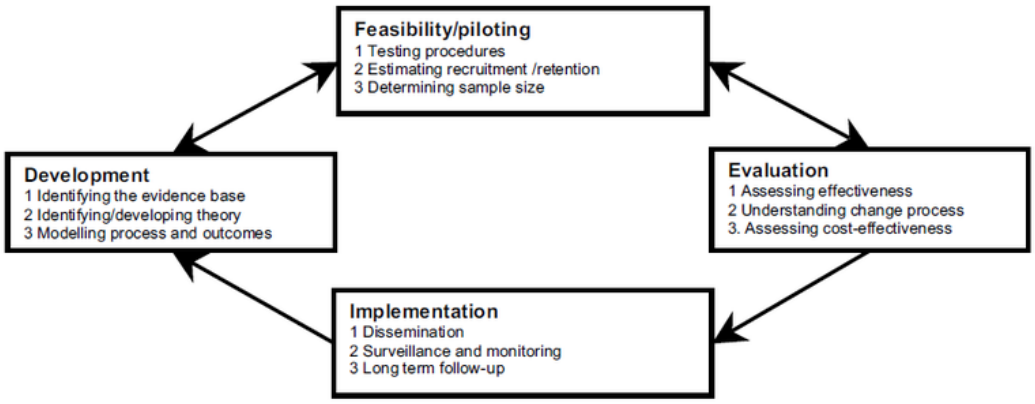

Figure 1.2 MRC Framework of Complex Interventions (MRC, 2000; Craig, 2008)

More recently, it has been recognised that the MRC frameworks provided insufficient guidance on how to conduct process evaluation to provide an understanding of the causal assumptions underpinning the interventions and evidence on how an intervention leads to change (Craig, 2013). A better understanding of how the intervention cause change will result in an intervention that is more likely to have a beneficial outcome and to be successfully implemented in practice (Craig, 2013). This has now been addressed and MRC guidance produced on approaches to process evaluation (Moore, 2015). This process evaluation of complex interventions is illustrated in Figure 1.3 below.

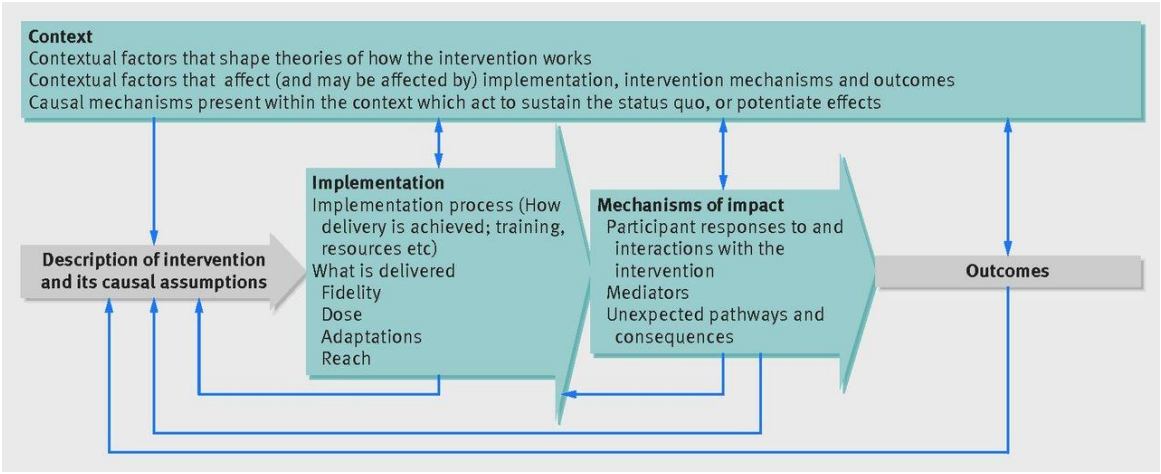

Figure 1.3 Process Evaluation of Complex Interventions: MRC Guidance (Moore, 2015)

In reviewing the theory on self-management and self-management education (Bodenheimer et al., 2002), the multi-component nature of self-management education and its use in addressing multiple factors in chronic disease management indicate that self-management interventions are complex. It is also clear from the previous sections

that the success of the intervention is dependent on patient, clinician, MDT team and organisational factors, reflecting the further layers of complexity outlined by Craig et al (2008) and the MRC complex interventions framework. It is also clear from the evidence reviewed in the previous section(s) that PR is also a clinical intervention with several interacting components, that description in itself, aligns PR with the description of a complex intervention as defined by the MRC (MRC, 2000). However, while there is good evidence about the effectiveness of PR, there is not good evidence to support the effectiveness of self-management within PR. While the MRC complex interventions framework would suggest that development should proceed evaluation and implementation, the research student was faced with the situation that the self-management component of PR was already being implemented in Liverpool. There were also time and resource constraints associated with a PhD programme of study, which meant it was not appropriate or feasible to complete the cycle of development and evaluation suggested by the framework. However, the researcher's experience of using the MRC complex interventions framework has suggested even though it was thought initially to be best practice to develop interventions systematically (Craig et al., 2013), that in practice, phases of development and evaluation do not always follow a linear or cyclical sequence (Campbell et al., 2007). Therefore, studying an existing complex intervention within practice contributes to aspects of the development and evaluation framework. These contributions include the refinement of theory, feasibility parameters for robust evaluation studies, development of implementation strategies, identifying appropriate outcome measures for process and outcome evaluation and monitoring and surveillance and understanding the reach of the intervention, e.g., who it works for (Craig, 2008; Moore, 2015). The findings of the thesis are discussed in relation to the MRC complex interventions framework (see thesis discussion in Chapter Six).

1.6 SUMMARY AND RATIONALE FOR THE THESIS

There is an abundance of evidence to support the benefits of PR for patients with COPD. However, although there is a significant amount of evidence to support the physical and health related quality-of-life benefits of PR for patients with COPD, the role of self-management education in COPD as part of PR has very little research based evidence to form recommendations for practice (Lacasse et al., 2009 and McCarthy et al., 2015). Cochrane reviews on self-management in COPD from the last decade (Effing et al., 2007; Effing et al., 2009; Zwerink et al., 2014; Lenferink et al., 2017), suggest that there is still insufficient data regarding this aspect of COPD management to form any recommendations for practice. In addition, the generalisability of the current evidence to the wider population of COPD patients who are mainly stable, i.e., not undergoing

exacerbation, could be questionable as a large proportion of the evidence on COPD self-management education currently are from studies where the patient cohort is mixed. These studies usually include patients who are either immediately post exacerbation of their COPD, in-patients who are mid-exacerbation or patients attending out-patient clinic settings with COPD self-management education delivered by a single or dual disciplinary health professional team. Therefore, there is a need to ascertain if self-management education as part of PR intervention has an impact on patient outcomes among the types of patients who attend these programmes. In the absence of a large-scale trial, exploration of the impact of a self-management course on patient outcomes within a routine PR programme could provide valuable insight into the effectiveness of integrating this strategy into PR. Such a study could explore whether there is a positive change in self-management outcome measures following delivery of a self-management course within a PR programme. It could also help to provide evidence towards whether self-management education strategies, as part of PR intervention, have a positive effect on other health outcomes through exploring the correlation between self-management and other clinical outcomes such as functional capacity, respiratory disability and emotional functioning. Such a study could serve to provide information to inform the design of future studies into this aspect of PR practice and to improve the quality of clinical services.

1.7 THESIS AIMS AND OBJECTIVES

Aims of the Thesis

The overall aim of this thesis was to understand the role and impact of self-management education for COPD patients within PR programmes, which will help inform the future design of these interventions.

Thesis Objectives

The overall objectives of the programme of study were:

1. To explore how self-management is delivered in PR services.
2. To explore the impact of a self-management education strategy on health outcomes.
3. To explore the relationship between self-management outcomes within a PR programme and functional capacity, respiratory disability and emotional functioning.

1.8 THESIS OVERVIEW

A brief description of the other chapters within this thesis is provided below.

Chapter Two

This chapter describes a survey of the delivery and evaluation of self-management education within PR programmes in the North West of England. It describes the variation in practices across different services and compares these with the approach within the Liverpool PR programme.

Chapter Three

This chapter describes a retrospective analysis of data held on the Liverpool PR administrative database. It outlines an exploration of the relationship between health outcomes and the BCKQ, as a measure of self-management, among 825 patients who attended between 01/09/2009 and 30/06/2011. The study suggested that the BCKQ may not be an adequate measure of self-management and led to the thesis aiming to identify and evaluate alternative measures of self-management.

Chapter Four

This chapter is a literature review using systematic methods on the health outcomes achieved by self-management programmes in COPD to identify components of self-management and appropriate outcome measures of the efficacy of self-management.

Chapter Five

Using measures of self-management identified from the literature review in the previous chapter, this chapter describes the findings from a prospective study of the relationship between these measures and other patient outcomes.

Chapter Six

This final chapter brings together all the findings from the studies described in this thesis and discusses their implications for clinical practice and research. There is also an outline of the impact of the thesis on the Liverpool PR programme.

CHAPTER TWO

A SURVEY OF THE SELF-MANAGEMENT EDUCATION STRATEGIES USED IN PULMONARY REHABILITATION SERVICES IN THE NORTH WEST OF ENGLAND

2.1 INTRODUCTION

In the previous chapter, background information on COPD and COPD management strategies including PR were described. It is important to note that, when the PhD started, the number of Pulmonary Rehabilitation (PR) services in the UK was unknown and the format of the different services used to deliver PR was also unknown. This chapter describes a survey of PR services in the North West of England. It outlines the process undertaken to identify PR services and characterise their service, particularly in regard to their self-management strategies, following which the findings of the survey are reported and discussed. Before doing this, the Liverpool PR programme is outlined, to allow the survey, and the pursuant studies, to be put into context.

2.2 REFLECTION ON THE RESEARCH JOURNEY

In reviewing the literature for the introductory section of the thesis, it became apparent to me that PR had evolved and continued to change over time. My thinking was that the next evolutionary stage for PR would be the incorporation of self-management education within the rehabilitative process with PR being an integral part of a holistic continuum of care for COPD patients. However, I also became increasingly aware of the limitations that the lack of a standardised PR programme and the lack of research or clinical guidance on self-management posed. I felt at this stage that rather than having an established path to guide my research, I was forging my way through relatively unexplored territory in PR, as a novice researcher, this has meant a steep learning curve but one that has challenged me to develop my knowledge and understanding of this subject area as well as research skills.

I had started this journey with the assumption that I could evaluate the impact of the Liverpool PR self-management education on health outcomes for patients with COPD, and found that I was unable to compare the Liverpool strategy I had developed to any other service in the NHS as the relevant information required to do that did not exist. I found that I had to take a step back to benchmark the Liverpool PR self-management education strategy to that utilised by other PR services, otherwise, I would not be able to generalise any findings to the wider population or make recommendations that may be relevant to PR research or clinical practice.

2.3 PULMONARY REHABILITATION IN LIVERPOOL

The empirical studies forming this PhD thesis were undertaken at the Liverpool Heart and Chest Hospital. This project site is based in Liverpool, one of the largest cities in the North West of England. According to the Office for National Statistics (2010), the North West of England has the second highest prevalence of smoking in England (see Table 2.1 and Figure 2.1), the highest prevalence of smoking among men in England (25%) and the third highest prevalence of smoking among women in England (22%).

Table 2.1 – Prevalence of Cigarette Smoking in England (Office for National Statistics, 2010)

	Percentage Prevalence of Cigarette Smoking	
	Men	**Women**
North East	17	23
North West	25	22
Yorkshire and the Humber	24	25
East Midlands	20	19
West Midlands	21	19
East of England	20	18
London	21	18
South East	21	18
South West	21	22
All England	21	20

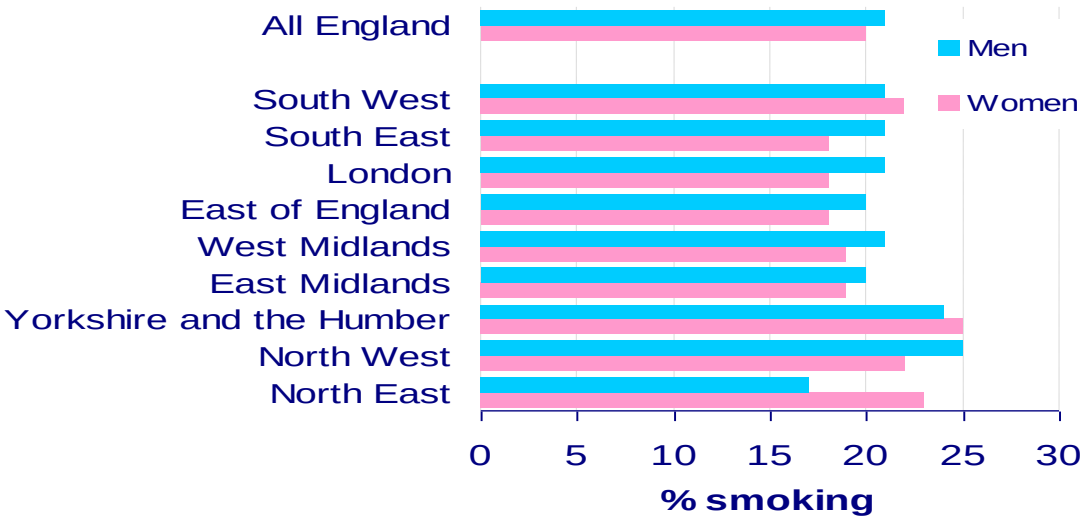

Figure 2.1: Prevalence of cigarette smoking by sex, England and Government Office Regions, 2008 (Office for National Statistics, 2010)

The extent of the public health challenge in Liverpool is reflected in the Liverpool Public Health Annual Report (PHAR, 2011), which reported the following findings:

- The prevalence of smoking in Liverpool is 28%, the highest rate in the North West of England and significantly higher than the national average for England of 22.2%.
- Liverpool has the highest death rate from smoking-related conditions in the North West and the second highest death rate from smoking-related conditions in England.
- The prevalence of COPD in Liverpool is 2.5% with the average for the North West being 2.0% and the national average for England being 1.5%.

In 2007, a British Lung Foundation project using data sources such as hospital admissions data and COPD GP surgery registrations data from the Department of Health identified Liverpool as a COPD "hotspot" (see Table 2.2), and flagged the city as facing the third greatest challenge against COPD in the UK (British Lung Foundation, 2007). A "hotspot" was defined as an area facing the greatest overall challenge from COPD considering the proportion of predicted COPD hospital admissions and the population size compared rest of the UK.

Table 2.2 – Top 10 COPD "hotspots" in the UK (British Lung Foundation, 2007)

Listing	Primary Care Organisation	Target Population
1	Glasgow	19%
2	Lanarkshire	56%
3	Liverpool	35%
4	Hull	40%
5	Sunderland Teaching	39%
6	Manchester	34%
7	County Durham	25%
8	Sandwell	36%
9	South Tyneside	43%
10	Gateshead	28%

The PR programme based at the Liverpool Heart and Chest Hospital was set up in accordance with National Institute for Clinical Excellence (NICE) guidelines on the management of COPD (NICE, 2004). These recommend that a pulmonary rehabilitation programmes should include multicomponent, multidisciplinary interventions, which are tailored to the individual patient's needs and that the rehabilitation process should incorporate a programme of physical training, disease education, nutritional, psychological and behavioural intervention (NICE, 2004; NICE, 2010). A process of service remodelling was undertaken in early 2009 and it was subsequently developed

into a programme with health outcomes that were monitored for each patient at three key stages: initial assessment, on completion of the programme and three months after the programme (see Appendix 1 for service model). Service provision was divided between five community-based clinics in different parts of Liverpool and one hospital-based clinic for patients with more severe disease category, patients on oxygen or patients who require assistance with transportation due to a medical condition.

The service was commissioned by Liverpool Primary Care Trust (PCT), now Liverpool Clinical Commissioning Group, and was accessible to all Liverpool residents registered with a General Practitioner (GP) within their boundaries. Referrals to the service were made in writing on a referral form and come from primary care, secondary care and tertiary care. The main sources of referrals from primary care were GPs, practice nurses, community matrons, Allied Health Professionals (AHPs), such as physiotherapists and community-based pharmacists from the Liverpool Medicines Management team. The main sources of referrals from secondary care were from neighbouring acute NHS Trusts in Liverpool, although other secondary care hospitals from outside Liverpool can refer Liverpool residents under their care to the service. The majority of referrals from secondary and tertiary care were from consultant chest physicians and other medical staff, nursing/specialist nursing staff and AHPs, such as community or hospital based physiotherapists or occupational therapists.

The referral criteria for PR were as follows:

- Liverpool resident registered with a Liverpool GP
- confirmed diagnosis of COPD
- MRC Dyspnoea Scale of Grade 3 or more or those at risk of worsening MRC Dyspnoea Scale score
- cardiovascularly stable to participate in exercise
- compliant with medication and consents to participate in the full programme.

The exclusion criteria for PR were as follows:

- unstable angina
- acute Left Ventricular Failure (LVF)
- uncontrolled hypertension/arrhythmia
- myocardial infarction (MI) within 6 months of commencing rehabilitation
- compliance issues likely to affect participation in PR.

Patient referrals were triaged and allocated to either the community-based or the hospital-based programme depending on the severity of their disease, the patient's mobility and their oxygen dependency status. The severity of the disease was categorised using a severity classification and score system (see Table 2.3).

Table 2.3 - Classification of COPD (The BTS COPD Consortium, 2004)

Classification of COPD		
Score	**Severity of Airflow Obstruction**	**FEV1 % Predicted**
0	Normal	FEV1 >80%
1	Mild COPD	FEV1 50 – 80%
2	Moderate COPD	FEV1 30 – 49%
3	Severe COPD	FEV1 <30%

*FEV1 - Forced Expiratory Volume in 1 second

Patients with a Forced Expiratory Volume in 1 second (FEV1) of ≤ 35%, patients who require supervision/assistance with mobility, patients who required hospital transport due to medical reasons, patients who were on prescribed oxygen or those who were non-Liverpool GP patients under the care of a Liverpool Heart and Chest consultant were allocated to the hospital programme. All other Liverpool GP patients were allocated to the community-based PR programme, based on geographical location or if requested, by the convenient day of the day of the week from Monday to Friday.

The assessment format for the community and hospital-based services are identical, although the more complex hospital-based assessments are allocated an hour compared to 45 minutes at the community-based clinics. The clinical assessment team consists of a senior respiratory physiotherapist and an exercise physiologist. The assessment team collate patient demographic information, such as, name, address and date of birth and collect other data such as next of kin details. In addition, the patient's physical suitability for the programme is assessed through a review of their blood pressure (BP), heart rate (HR), oxygen saturation levels (O2) and the patient's levels of exertion using the Borg rating of perceived exertion (RPE) scale (Ward and Bar-O, 1990). If the patient's physiological measures are deemed to be within normal ranges, a variety of tests used as outcome measures for the programme are then carried out with the patient. These outcome measures are assessed prior to commencing rehabilitation to establish a baseline for each patient. The outcome measures for PR at the Liverpool Heart and Chest Hospital were determined by the service level agreement set by the commissioners of the service.

These were:

a) Functional capacity – Walk Test
b) Respiratory disability – Medical Research Council (MRC) dyspnoea scale
c) Emotional functioning – Hospital Anxiety and Depression Scale (HADS)
d) Self-management – Bristol COPD Knowledge Questionnaire

Walk Test

Simple walking tests are widely used for the assessment of functional status in patients with cardiorespiratory disorders such as COPD as they require far less instrumentation than other types of cardiopulmonary exercise tests (Wise and Brown, 2009). In the Liverpool PR service, two different types of walking test were used to measure functional capacity, namely, the Incremental Shuttle Walk Test (ISWT) and a Six Minute Walk Test (6MWT). The ISWT and the 6MWT are the most widely used tests for patients with COPD (Wise and Brown, 2009). In addition to the practicalities of less instrumentation, Alison et al. (2009) and Singh et al. (2014), outline three reasons for the use of the ISWT and the 6MWT in clinical practice:

- The distance walked has a moderate to strong correlation with peak oxygen uptake (peak VO2) in patients with moderate to severe COPD
- The ISWT and the 6MWT are both potentially a symptom limited maximal test in this patient group
- Exercise prescription for the PR programme can be calculated from the results of the test based on percentage of the average speed (6MWT) or maximal speed (ISWT) achieved

The ISWT is an externally paced maximal exercise test, controlled by a set of pre-recorded signals, where the speed of walking increases with each level (Holland, Spruit and Singh, 2015). During the ISWT, the patient is required to walk around two cones placed nine metres apart, to provide a total walking distance of 10 metres called a shuttle. The ISWT requires the patient to walk at a pace set by recorded auditory bleeps that progressively speeds up at one-minute intervals (Singh et al., 2008). Standard prompts to increase speed can be used at those intervals to encourage the patient to pick up their pace. The assessor should keep record of the number of shuttles walked, pace and clinical observations of the patient. The ISWT should continue until the participant indicates they can no longer continue or cannot keep up with the required pace or the assessor determines that the patient is not fit to continue with the test or keep up with the pace. The ISWT is responsive to changes with interventions in patients with COPD (Singh et al., 2014). The change in distance walked in the ISWT can be used to evaluate

the efficacy of an exercise training programme and suggest an improvement of 47.5 metres indicates that patients with COPD are “slightly better” and an improvement of 78.7 metres represents “better” (Singh et al., 2008). A change of 47.5 metres (five shuttles) or more is considered clinically meaningful (Holland et al., 2015).

In contrast to the ISWT, the 6MWT is described as a self-paced test of walking capacity (Holland et al., 2014) with the choice to stop, rest or terminate the test at any stage during the period of the test. Patients are asked to walk as far as possible in six minutes and the distanced walked in that time is recorded. Standardised instructions and encouragement can be given during the test (ATS, 2002). The 6MWT is responsive to change observed with common treatments in COPD (Holland et al., 2015). Findings of a systematic review of measurement properties for walking tests in respiratory disease by Singh et al. (2014) reported that the 6MWT is a reliable measure with intra-class correlation coefficients ranging from 0.82 to 0.99. The 6MWT demonstrates good construct validity with correlation coefficients of 0.40 – 0.93 with maximal exercise performance and physical activity (Holland et al., 2015). The minimum important difference in the distance walked in the 6MWT has traditionally been estimated at 54 metres (with 95% confidence limits 37 to 71 metres) [Redelmeier,1997], although more recently, Puhan (2008) identified a distance of 35 metres (95% confidence limits of 30 to 42 metres) as representing an important effect in COPD. Holland et al. (2014) established a change of 30 metres as being considered to be clinically important. However, it is important to bear in mind that, Puhan et al. (2008) found that smaller improvements in 6MWT distance may occur in patients who walk a very short distance (less than 200 metres) and suggested a percent change of 10% as being clinically important in COPD.

Although the ISWT is more standardised due to the use of an external pacing mechanism, there is a floor effect, meaning that in practice, the ISWT could not be used for a significant number of patients, i.e., those unable to maintain the pace of the test (Alison et al., 2009; Singh et al., 2014). Therefore, in clinical practice within the Liverpool PR service, the type of walk test chosen for each patient was determined by the disability level of the patient (Alison et al., 2009). The 6MWT was chosen over the ISWT for more disabled patients, patients with an impaired stride length due to co-ordination or musculoskeletal problems, patients who use a mobility aid and patients unable to walk at a speed >1.8km/hr (Alison et al., 2009), as they are unable to keep up with the increasing pace of the ISWT. Although research shows that supplementary oxygen affects 6MWT and ISWT performance (Singh et al., 2014), patients on ambulatory oxygen were routinely assessed using the 6MWT rather than the ISWT. This was due to the potentially limiting challenge(s) for both the patient and the assessing clinician in the coordinating of

manoeuvring of ambulatory oxygen apparatus around the walking circuit while carrying out the other assessment requirements for the walk test.

In accordance with ERS/ATS standards (Holland et al., 2014), Liverpool PR assessment guidelines required that the patient's BP, HR, SpO2 and dyspnoea scores using the Borg dyspnoea scale are measured before and after the walk test. The HR and SpO2 are monitored throughout the walk test in addition to physical observation of the patient's respiratory rate, respiratory pattern and breathlessness levels by the assessing clinician as well as self-reported symptom severity by the patient being assessed (see Appendix 2). Regardless of the choice of walk test, the walk test is a patient-governed procedure and the test can therefore be terminated at any point by the patient. The assessing PR clinician can also terminate the walk test early in the following circumstances:

1. The patient's HR is > 80% of the submaximal HR expected for their age
2. The patient is unable to keep up with the pace with the bleep test or is fatigued
3. The patient is short of breath
4. The patient's SpO2 drops >5%
5. Other reasons such as pain, discomfort, etc.

MRC (Medical Research Council) Dyspnoea Scale

Breathlessness is a complex subjective sensation that is an important feature of cardio-respiratory disease. It is difficult to quantify but it is necessary to do that if the symptoms of a particular group are to be summarised and compared with others. According to the Society of Occupational Medicine (2008), Fletcher et al. developed the scale while studying the respiratory problems of Welsh coal miners at the Medical Research Council Pneumoconiosis Unit in the 1940s. They devised a short questionnaire that allowed a numeric value to be placed on each subject's exercise capacity. The questions were first published in 1952 (Fletcher et al., 1952) and rapidly developed into the MRC breathlessness scale (Fletcher et al., 1959). The MRC dyspnoea or breathlessness scale (see Table 2.4) comprises five statements that describe almost the entire range of respiratory disability from none (Grade 1) to almost complete incapacity (Grade 5). It is usually administered by asking the subjects to choose a phrase that best describes their condition (The Society of Occupational Medicine, 2008).

Table 2.4 – The MRC breathlessness scale (Bestall et al., 1999)

Grade	Degree of breathlessness related to activities
1	Not troubled by breathlessness except on strenuous exercise
2	Short of breath when hurrying on the level or walking up a slight hill
3	Walks slower than contemporaries on level ground because of breathlessness, or has to stop for breath when walking at own pace
4	Stops for breath after walking about 100m or after a few minutes on level ground
5	Too breathless to leave the house, or breathless when dressing or undressing

Hospital Anxiety and Depression Scale (HADS)

The HADS is a brief and widely used instrument to measure psychological distress in different patient groups (see Appendix 3). There is evidence that the HADS gives clinically meaningful results as a psychological screening tool, in clinical group comparisons and in studies with several aspects of disease and quality-of-life (Montazeri et al., 2003). The HADS is sensitive to change both during the course of the disease and in response to medical and psychological intervention (Hermann, 1997). The HADS discriminates well between samples with high, medium and low prevalences of anxiety or depressive disorders (Herrmann, 1997). The minimal important difference for the HADS is approximately 1.5 points in COPD (95% CI 1.38 -1.82), corresponding to a change from baseline of around 20% (Puhan et al., 2008). Bjelland et al. (2002) in a review of the literature on the validity of the HADS showed that the HADS demonstrated good internal consistency with Cronbach's alpha coefficient of internal consistency varying from 0.68 to 0.93 for HADS-A (mean 0.83) and for HADS-D from 0.67 to 0.90 (mean 0.82). A value of at least 0.60 is recommended for a self-report instrument to be reliable (Nunnally and Bernstein, 1994). The test-retest reliability for the HADS showed high correlation of $r>0.80$ (Herrmann, 1997; Bjelland et al., 2002). According to Montazeri et al. (2003), the HADS anxiety and depression scores showed a negative but significant correlation with emotional function ($r=-0.70$, $p<0.0001$) and global quality-of-life ($r=-0.77$, $p<0.0001$), meaning that those who were more anxious or depressed showed lower levels of emotional functioning and global quality-of-life. The HADS has been found to perform well in assessing symptom severity of anxiety disorders and depression in both somatic, psychiatric and primary care patients (Bjelland et al., 2002).

Bristol COPD Knowledge Questionnaire (BCKQ)

During the PR service remodelling process in 2008/2009, the Liverpool commissioners identified the evaluation of functional capacity, emotional functioning and self-management as part of a quality assurance component of the service. The service level

agreement required the use of the BCKQ as the outcome measure for self-management. The service was required to report on all health outcomes annually as part of the service level agreement between the commissioners and the NHS Trust. This decision was made based on the 2003 definition of self-management by Bourbeau (Bourbeau, 2003): The BCKQ is a questionnaire specifically designed to test the disease specific knowledge of patients with COPD. The BCKQ is a validated tool, which has been shown to be responsive to educational intervention (White et al., 2006). The BCKQ has been assessed as having good test re-test reliability (r = 0.71), good content validity, good face validity and good internal consistency (Cronbach's alpha 0.73) (White et al, 2006). It tests knowledge that is appropriate for COPD patients and enables the effectiveness and cost-effectiveness of education to be assessed.

The BCKQ is a self-report, multiple-choice questionnaire that covers 13 vital aspects of COPD pathology and management (see Appendix 4) in 13 sections. These sections cover epidemiology and physiology, aetiology, common COPD symptoms, breathlessness, phlegm, chest infections, exercise, smoking, immunisation, inhaled bronchodilators, antibiotics, oral steroids and inhaled steroids. Each of the 13 topics contains five statements for which there is a right or wrong answer, giving a total of 65 questions. The respondent is required to indicate whether each statement is “True” or “False” or if they “Don’t know” whether the statement is true or false. Positive scoring is used with a mark (1 point) being given for a correct answer but no mark (score of zero) being awarded for an incorrect answer or a “Don’t know” response. The minimum score for the BCKQ is zero and maximum score possible is 65, with higher scores suggesting better knowledge. It is important to note that these 13 sections are not constructed as subscales.

White et al. (2006) concluded that the BCKQ is suitable for both clinical and research purposes, and it can be used as an assessment tool for individual patients, or as a broad cross-sectional survey instrument. In the Liverpool programme, the BCKQ is used to measure the patient’s knowledge of their condition before the programme to establish a baseline and after completing the PR programme to measure the intervention effect. The burden on the respondent is relatively low with the questionnaire being completed in 15 – 20 minutes.

The Rehabilitation, Re-assessment and Follow-Up Assessment Process

The PR programme consisted of an exercise and a self-management education component. The exercise component was an hour long and consisted of the following:

- A warm up session to prepare the body for exercise using a combination of joint range of movement, muscle stretching and cardiovascular low intensity exercises
- A priority of modes exercise circuit of cardiovascular, endurance, muscle strengthening (upper and lower limb) as well as breathing control exercises all in conjunction with pacing mechanisms and breathlessness management strategies
- A cool down session using a combination of very low intensity cardiovascular exercises, joint range of movement and muscle stretching exercises to aid recovery post exercise

The self-management education component consisted of a weekly formal interactive session, which was also an hour long and, over the eight weeks, covered a variety of topics delivered by different health care professional groups. Each session was designed to increase the patient's knowledge of their condition, increase their ability to manage it and to encourage lifelong commitment to exercise and a healthier lifestyle. The eight education sessions included topics such as the aetiology and management of COPD (including the management of infective and non-infective exacerbations, i.e., flare-ups of the condition), managing breathlessness, COPD medication management, managing stress or anxiety and energy conservation, exercise, nutrition, environmental health and support services for COPD. The theoretical self-management education was supported by practical skills training such as inhaler techniques, pacing techniques, dyspnoea management exercises, chest clearance exercises +/- chest clearance device such as an Acapella or Flutter and physical activity coaching.

All outcome measures were reassessed after the patient completes all eight sessions of the PR programme to evaluate the patient's response to PR intervention. Following reassessment, a home maintenance programme consisting of the options of a walking programme, a Home Exercise Programme (HEP), gym, further rehabilitation, Exercise for Health scheme or a combination of these options were discussed and agreed with the patient (See Appendix 1 – Service Model).

Three months post completion of the programme, the patient's response to their maintenance programme was evaluated using the same measures. If the patient and the clinical assessor were both satisfied with the outcomes achieved, the patient was discharged at that stage. The patient's maintenance programme could be altered with a recommendation for follow up with the referrer being made on discharge to evaluate the patient's progress following discharge from PR, if this was deemed appropriate. On

completion of the programme, the normal procedure was for the patient's results to be reported to the referrer in a summary table similar to Table 2.5, in addition to a discharge report from the final assessment of the patient.

Table 2.5 – Summary of Outcome Measures

	INITIAL ASSESSMENT	RE-ASSESSMENT	3/12 REVIEW
Shuttle (metres)			
HAD Anxiety			
HAD Depression			
MRC			
BCKQ SCORE			

All patient data and outcome measures from the three assessment stages were recorded on a PR database. The PR database was an electronic record of patient demographic, pathology and PR outcome measures. By 2010, there was approximately eight years' worth of data for the SWT and the HADS and approximately three years' worth of data for the BCKQ and the MRC dyspnoea scale scores.

Patients who did not want to attend the programme were discharged and a copy of the discharge letter was sent to the referrer, the patient, as well as, to the patient's GP (if not the referrer). Patients who were unable to attend the programme for health, personal or other reasons were offered the option to be put on hold for up to 12 weeks pending the resolution of the problem. They were routinely offered a review if they wished to restart the programme before the end of the 12-week suspension period. If the patient was still unable to restart the programme at the end of the 12-week period and they felt that the situation would not be resolved within a reasonable period, they were discharged from the programme with a copy of the discharge letter which was also sent to the referrer and the GP (if not the referrer). Patients who DNA two consecutive appointments or sessions were contacted initially by phone, then followed up by written correspondence, if required. They are discharged from the programme if they did not contact the team within two weeks of the letter being sent out. A discharge letter was sent to the referrer, the patient and the patient's GP (if not the referrer).

2.4 RATIONALE FOR A SURVEY OF NORTH WEST PULMONARY REHABILITATION SERVICES

At the time of the survey in 2010, there was no standard format for PR in the United Kingdom. The British Thoracic Society (2001) in reviewing the evidence for PR recommended between 8 – 12 sessions and different PR services offered varying numbers of sessions as part of their PR programmes. There was also no standard number of PR sessions per week, although the British Thoracic Society (2001) guidelines recommended an average of two supervised sessions per week. Again, different programmes offered a variety of supervised sessions per week.

An overview of the literature available on PR outlined in Chapter One demonstrated that the definition of PR is broad and the structure and processes of PR evaluated in RCTs was quite varied. The evidence of the effectiveness of PR from RCTs is restricted to specific components of PR, such as physical training or response to medication based intervention (Harris, 2008; NICE, 2010; McCarthy et al., 2015). But, there is a lack of evidence on the efficacy of self-management in PR or clinical guidance as to what it should entail; although, the current evidence is that self-management education alone is insufficient to effect the change in patients (Wood-Baker et al., 2012). This aim of thesis is to understand the concept of self-management within PR, utilising data from the Liverpool PR service to explore this concept. Therefore, before proceeding with studies involving this service, it was important to understand more about the delivery of self-management education within PR programmes in practice. It was also important for the generalisability of the pursuant study findings to know if the Liverpool PR programme is in line with current service provision. Therefore, a survey of PR services was undertaken.

According to the Kings Fund (2010), there were 152 Primary Care Trusts (PCTs), the unit of health organisation at that time, in England, reduced from 303 in October 2006. Due to the high number of PCTs in England, the decision was taken to limit the initial exploration about self-management education in PR to the 24 PCTs in the North West of England. The characterisation of self-management education strategies through this process will also enable the researcher to inform the design of the pursuant studies of the impact of self-management education as part of PR on health outcomes for COPD patients.

2.5 METHODOLOGICAL APPROACH

For the purpose of this study, understanding the constituents of other PR services, how the different components are delivered, how often and by whom, were important for this

research student to compare the Liverpool PR practice to other PR services. Although a qualitative or quantitative approach could have been used to gain this understanding, a quantitative approach was deemed to be most appropriate because the primary purpose of this exercise was to obtain data on the format and structure of other PR services and to enable comparison, rather than gaining insight into clinicians' opinions on how their services are run. Findings from quantitative studies are useful in establishing the replicability and generalisability of an approach (Parahoo, 2014). As the means used to get data depends on the nature of the data to be sought (Blumer, 1969; Parahoo, 2014), the use of a quantitative approach to establish the generalisability of the Liverpool PR approach in this instance, was justifiable. A quantitative approach enables the researcher to measure the research concepts or variables (Waltz et al., 2010). In order to meet the objectives of this study, it was important to be able to have a measure of the concepts and variables being explored, therefore providing further justification for the use of a quantitative approach over a qualitative one.

Descriptive research is a most basic type of enquiry that aims to gather information on certain phenomena, typically at a single point in time and are used to estimate specific parameters in a population (Kelley et al., 2003). Although there are different methods by which this information could have been gathered, a survey design was deemed to be a suitable initial step towards gaining insight into the constituents of PR services and how different Trusts run these services. A survey is a research method by which information is typically gathered by asking a subset of people questions on a specific topic and generalising the results to a larger population (Groves et al., 2004; Aday et al., 2006; Check and Schutt, 2012). More specifically, a cross-sectional survey was chosen as this type of survey aims to examine a situation by describing important factors associated with that situation, such as demographic, socio-economic, and health characteristics, events, behaviors, attitudes, experiences, and knowledge (Kelley et al., 2003). Surveys can be administered using open-ended, closed-ended or a mixture of open and close-ended questionnaires. As the information required from this survey was specific and required for comparative purposes, a close-ended questionnaire format was chosen to administer the survey, especially as open-ended questions have been found to be more demanding for respondents (Kelley et al., 2003).

There are different methods of delivering a survey, face-to-face delivery, online, postal or telephone delivery. The use of an online method of delivery was dismissed because at the time of the survey, many PR services, especially community based services sited in community centres or church halls did not have internet access. As the survey was

conducted in work time, this lack of internet access may have impacted negatively on the ability of participants to respond or participate in the survey. The telephone method of delivery was chosen instead of a face-to-face delivery for three reasons. First, telephone surveys allow a two-way interaction between the research student and the respondent. Second, telephone surveys are quicker and cheaper than face-to-face interviewing (Kelley et al., 2003) and due to the limited resources available to the research student to travel to meet the different PR service leads to conduct the survey, it was important to keep costs at a minimum. The third reason was that it was important to maximise recruitment of willing study participants by minimising the burden on potential study participants, due to time limitations of busy clinical leads with high workloads. The risk of a poor response rate from a postal survey or incomplete questionnaires, dissuaded this research student from this method of survey delivery: Postal survey response rates are generally low, approximately 20%, depending on the content and length of the questionnaire (Kelley et al., 2003). In addition, by emailing the survey questionnaire in advance and then following up with the telephone survey, participants were able to access the questionnaire before the telephone survey was conducted, therefore enabling them to prepare sufficiently for the survey, thereby, reducing the overall time taken to conduct the survey.

Due to the time constraints of the programme of study, it was imperative to have a manageable sample size for analysis in the available timeframe. Unlike secondary care, there is no national database of PR services from which to construct a sampling frame. Therefore, the practical decision was made to utilise the networks across the North West of England to identify a set of services that could practically be surveyed. The decision to limit the survey to the North West of England, rather than a national perspective, was primarily driven by resource constraints as this study was conducted by a lone research student. Networks across the North West of England were used to verify the identity of PR services and contact details for service leads across the region.

2.6 SURVEY OBJECTIVES

The objectives of this survey were:

1. to describe the service profile of the PR services in the North West of England
2. to identify how many services incorporate self-management education into their PR programmes across the North West of England
3. to ascertain the context, format and means of delivery of the self-management education component of the PR programmes across the North West of England
4. to identify the methods for evaluating the impact of the self-management education used by PR services in the North West of England.

2.7 METHOD

2.7.1 Study Design:

This was a cross-sectional telephone survey using a questionnaire tool. The survey was used to collect information regarding the structure, content and evaluation of self-management education strategies used as part of routine practice in PR services.

2.7.2 Setting

The survey was carried out among PR services across primary, secondary and tertiary healthcare organisations in the North West of England.

2.7.3 Participants

The Department of Health's (DoH) website was used to identify NHS organisations in the North West of England. The health organisations in the North West of England that run a PR service for COPD patients were cross-referenced with the North West Strategic Health Authority PR survey contact list from 2010 and by liaising with the British Lung Foundation North West. Once the PR service was identified, the clinical lead for each service was identified by liaising with fellow clinicians via local networks and iCSP (interactive networking website for physiotherapists who are registered members of the Chartered Society of Physiotherapists) and by direct liaison with listed Primary Care Trusts (PCTs) via telephone to identify a PR service lead. Once identified, the clinical lead for each PR service was approached to undertake the survey.

Inclusion Criteria

Any NHS based organisation with a PR service based in NHS health organisations in the North West of England was included in the survey.

Exclusion Criteria

Any NHS based health organisation that was not routinely involved in the care of patients with COPD as part of its primary specialties and does not have an identified PR service for COPD patients was excluded from the survey.

2.7.4 Ethical Considerations

The research student confirmed with the NHS Trust Research and Innovation Lead that at the time of the survey NHS ethics approval was not required and that the survey could be considered service evaluation as it contained no personal or organisational identifiable content (see Appendix 5). In line with University policy, approval from the Faculty of Health's research ethics committee at the University of Central Lancashire

only was therefore sought and obtained (Appendix 6). Informed consent to participate in the survey was obtained from all participants approached to take part in the survey. Stringent steps were taken to ensure confidentiality in the recording and storage of both electronic and hard versions of data so that there were no person/organisation identifiable information included.

2.7.5 Data Collection Tool

In order to build up a descriptive profile of the components of PR services, the survey utilised a self-completed questionnaire to ensure that the information required to meet the objectives of the survey was obtained in full and consistently. The data was collected over the telephone to increase the response rate from busy clinicians.

2.7.6 Questionnaire development

The first stage in the development of the questionnaire was to consider what question format would provide the most accurate and complete data for the areas of interest. The decision was taken to formulate a closed-question format in the questionnaire in order to maintain focus on the self-management education component of PR and to minimise the burden on the participants by having a relatively brief questionnaire due to the time constraints of busy clinicians. Careful consideration of the aims and objectives of the survey, personal experience of running services and the review of the literature on PR informed the content of each question.

As a result, the questionnaire was designed to provide the following information regarding PR services (see Appendix 7):

1. The type of the service – hospital or community based.
2. The content of the programme, i.e., exercise, self-management education or both.
3. How respective components are delivered and by whom.
4. The components of the self-management education programme.
5. The format of delivery for the self-management education programme.
6. The evaluation of the self-management education programme, i.e., what methods are used to assess patient's knowledge of their condition and changes in their knowledge.
7. The follow up protocol and practice for the programme, i.e., timing, frequency and assessment processes.

A multiple-choice answer format was applied to the questions not requiring a Yes or No response. The response options chosen for the multiple-choice questions were based on parameters stipulated in PR related guidelines from the British Thoracic Society's 2001 statement, the CSP's 2003 guidance for physiotherapists and the NICE guidelines updated in 2010 (BTS, 2001; CSP, 2003, NICE, 2004; NICE, 2010).

2.7.7 Pre-Pilot of the Questionnaire

A pre-pilot to test the design of the questionnaire was carried out involving a group of five senior clinicians based locally in Liverpool, who were currently working or had previously worked in PR or were currently leading or had previously led a PR service. These clinicians were then not eligible to be included in other stages of the survey. Once identified, each clinician was contacted by the research student by telephone. A verbal explanation of the purpose of the survey was given and the potential participant was asked to consider participating in the survey. If they were willing to consider participating in the study, the potential pre-pilot participants were sent a pre-pilot cover e-mail (Appendix 8), a participant information sheet explaining the purpose of the pre-pilot (Appendix 9) and the questionnaire (Appendix 7).

Potential participants were asked to e-mail their decision about whether they wished to participate or not to the research student. If they did not respond to the e-mail within one week, the research student contacted the potential participant by telephone to confirm receipt of the e-mail and to ask them if they could confirm in an email whether they wished to participate or not to participate. Subsequent to the follow up telephone call, if the potential participant still did not respond, the research student would assume that they did not wish to participate in the survey and did not contact them again. If they agreed to participate in the study, the research student contacted the participant by telephone to arrange a suitable date and time to participate in a telephone "think aloud" exercise in order for the research student to document feedback from the group regarding the questionnaire. According to Ericsson and Simon (1980), a think aloud protocol is a method in which the participant verbalises while they are completing a task. Each participant was asked to comment on the phrasing or structure of the questionnaire and how they might respond to the question based on their interpretation of the meaning of the question. Any observations that may require changes to be made to the questionnaire were recorded in writing by the research student but participants' actual responses to the questions were not documented.

2.7.8 Pre-pilot Results

Comments and observations requiring amendments to be made to the questionnaire were documented for three questions. These are outlined in the table overleaf (see Table 2.6).

Table 2.6 – Pre-Pilot Results

Question	Comments/Observations
Question 5 How long is your programme, i.e., number of weeks? Please tick only one option a) 1 week □ b) 2 weeks □ c) 3 weeks □ d) 4 weeks □ e) 5 weeks □ f) 6 weeks □ g) 7 weeks □ h) 8 weeks □ i) 9 weeks □ j) 10 weeks □ k) 11 weeks □ l) 12 weeks □ m) Other (Please list below) □ ……	1. Straight forward – how long is your programme? 2. Straight forward – how long is your PR? 3. Fine 4. Clear – how long is your programme? 5. Does that include assessment and end weeks or follow ups or just rehab sessions?
Question 18 Do you re-assess this on completion of your programme? If respondent answers No, the questionnaire is complete Yes □ No □	1. Straight forward 2. Straight forward 3. Fine 4. What are you referring to? If it is part of 17, it should be referred to as such. 5. Self-explanatory
Question 19 Do you routinely follow up patients following completion of pulmonary rehabilitation? Yes □ No □	1. Straight forward 2. Do you check on patient progress? 3. Makes sense – do you have follow up assessments 4. A bit of ambiguity. Needs to specify what this is. Completion of what? 5. Makes sense – do you follow up patients after PR?

Based on these responses from the think aloud exercise, questions 5, 18 and 19 were rephrased to improve the readability of the questionnaire and to reduce the chance of misinterpretation (Table 2.7). The amended questionnaire (Appendix 10) was subsequently used to pilot the method of survey delivery.

Table 2.7 – Survey Questionnaire Amendments

Question	Pre-pilot format	Post pre-pilot format
5	How long is your programme, i.e., number of weeks?	Excluding assessment, re-assessment and any follow up assessment sessions, how long is your programme, i.e., number of weeks?
18	Do you re-assess this on completion of your programme?	Do you re-assess patient knowledge on completion of your programme?
19	Do you routinely follow up patients following completion of pulmonary rehabilitation?	Do you routinely follow up patients once they have completed your programme?

2.7.9 Pilot: Method of Survey Delivery

Prior to sending an invitation to participate to the whole sample, the amended questionnaire was piloted with five of the identified participants, using the methods described above (see Appendices 11 and 12 for the pilot study cover email and the participant information leaflet). As the method of administration was considered satisfactory and the questions were answered appropriately and without the need for clarification, the survey was rolled out to the remaining eligible NHS Trusts. The data collected in the pilot were included in the final analysis.

2.8 SURVEY

Each clinical lead for the 27 PR services in the North West was contacted by the research student by telephone between 25/10/2011 – 05/11/2011. A verbal explanation of the purpose of the survey was given and the potential participant was asked to consider participating in the survey. If they were willing to consider participating in the study, they were sent a cover e-mail (see Appendix 13), a participant information sheet explaining the purpose of the main survey (Appendix 14) and the questionnaire (Appendix 15).

Potential participants were asked to e-mail their decision about whether they wished to participate or not to participate in the study to the research student. If they did not

respond to the e-mail within 1 week, the research student contacted the potential participant by telephone to confirm receipt of the e-mail and to ask them if they could confirm in an email whether they wished to participate or not to participate in the study.

In the instance that the potential participant still did not respond after the follow up telephone call, the research student would assume that they did not wish to participate in the survey and did not contact them again. If they agreed to participate in the study, the research student contacted the participant by telephone to arrange a suitable date and time to participate in a telephone survey with the participant. The research student contacted the participant at the appointment time to carry out the survey over the telephone. All responses to the questionnaire were documented in writing by the research student and then recorded on a database with each organisation allocated a study number.

2.8.1 Sample Size

The total number of NHS organisations offering PR to patients across the North West of England was unknown at the start of the survey. The Department of Health's (DoH's) North West NHS website provided details of 24 Primary Care Trusts in the North West, which were contacted by telephone to identify the existence of a PR service and the contact details for the leads for those services. The researcher cross-referenced this contact list with information already gathered from the North West Strategic Health Authority (SHA), local networks, the British Lung Foundation and iCSP to ensure that all the information was up to date and complete. In total, 27 PR services were identified and each service was then contacted individually to confirm the identity of the lead clinician.

2.8.2 Data Management

The questionnaire from each service was given a unique study number. Data from each questionnaire was initially inputted on an Excel spreadsheet with allocated cells for each service's response to each question. The response to each question was documented in writing by the research student during the telephone survey and typed unto the Excel spreadsheet once the hard copy of the questionnaire had been completed. The key to the study number was filed separately from the collected data in a locked cabinet to maintain anonymity. Once data collection was completed, the research student carried out verification checks on the transcribed information to ensure the information recorded was correct. The key was destroyed once all data has been collected to maintain the

anonymity of the trust and the participant. The hard copy of each questionnaire was stored in a locked cabinet separate from the study key.

2.8.3 Data Analysis

Each variable was coded and an SPSS study key created on a Word document to record the variable codes. The data from the Excel spreadsheet was then read into an SPSS data file. A final verification check of the data was carried out to ensure that there were no errors or missing information by the research student checking the typed response to each question to the original handwritten record. Analysis was performed to evaluate types of service provision, exercise programmes and education components used as part of routine PR intervention. The statistical analysis was descriptive and comprised predominantly of frequency and percentages to develop a profile of the different approaches used for PR in the North West.

2.9 RESULTS

All 27 identified PR leads consented to participate in the study, providing a final sample size for the survey study of 27 PR services, five of which had already participated in the pilot of the questionnaire. There were no missing data. The results of the survey are described in the following two sections; characteristics of the services and COPD self-management education strategies.

2.9.1 Characteristics of PR Programmes in the North West

The results of the survey describing the characteristics of the services surveyed were divided into five main categories:

1. Type of service
2. Settings of the rehabilitation programme
3. Professionals involved in service delivery
4. Attendance
5. Services offered

The results of the survey demonstrated variation in the different types of services, programme settings, staffing involved in the delivery of the respective PR programmes, duration of the programme, frequency of patient attendance and services offered as illustrated by Table 2.8. PR was delivered by primary care (59.3%), secondary care (33.3%) and tertiary care (7.4%) organisations. Services were community-based (51.9%), hospital-based (40.7%) or a combination of both (7.4%). PR services were provided by a range of health and social care professionals but 96.3% of services had a

physiotherapist, 59.3% had a respiratory nurse, 29.6% had a dietician and 29.6% had an occupational therapist. Duration of the PR programmes ranged from a minimum of four weeks to a maximum of 10 weeks. Frequency of attendance was limited to once or twice a week. PR services offered included access to oxygen (96.3%), Home Exercise Programme (HEP) (74.1%), HEP and equipment (18.5%). Over half, followed patients up after they completed the programme (59.3%). Further exploration of services for patients needing oxygen revealed that 10 primary care organisations (37% of services surveyed) and three secondary care organisations (11.1%) had community-based PR services for patients on oxygen, two secondary care organisations (7.4%) had hospital-based PR services for these patients while two tertiary care organisations (7.4%) offered both hospital-based and community-based PR services. One primary care organisation (3.7%) did not offer access to PR for patients on oxygen. The Liverpool PR service provides a hospital-based clinic for patients on oxygen.

Table 2.8 – Characteristics of PR Services Surveyed

Characteristic	Frequency of Occurrence	
Different types of services	Primary Care organisation (59.3%) Secondary Care organisation (33.3%) Tertiary Care organisation (7.4%)	
Different types of settings	Community based service (51.9%) Both hospital and community based service (40.7%) Hospital based service (7.4%)	
Staffing	Physiotherapist (96.3%) Nurse (59.3%) Dietician (29.6%) Occupational Therapist (29.6%) Assistant Practitioner (14.8%) Pharmacist (11.1%) Physiotherapy Assistant/Technical Instructor (11.1%) Exercise Physiologist (7.4%) Exercise Professional/Trainer (7.4%) Counsellor (3.7%) Doctor (3.7%) Exercise Referrals Officer (3.7%) Healthy Lifestyles Officer (3.7%) Pharmacy Technician (3.7%) Support Worker (3.7%) Volunteers (3.7%)	
Visits	**Duration of programme:** 8 weeks (55.6%) 6 weeks (29.6%) 7 weeks (7.4%) 4 weeks (3.7%) 10 weeks (3.7%)	**Required attendance:** Twice a week (85.2%) Once a week (14.8%)
Services offered	Access for patients on oxygen (96.3%) Provide HEP consisting of an exercise routine (74.1%) Provide HEP of exercise routine and equipment (18.5%) Offer routine patient follow-up post completion (59.3%)	

2.9.2 COPD Self-Management Strategies

All services had some educational input but there was wide variation in the self-management or patient education topics covered by the different PR services across the region as demonstrated in Table 2.9. All covered disease management and most symptom management but about a fifth did not include stress or anxiety management and only two-thirds covered smoking cessation.

Table 2.9 – Self-Management Education Components

Self-Management Education Topic	Frequency	Percentage
Disease management	27	100%
Medication	26	96.3%
Energy conservation	26	96.3%
Symptom management	25	92.6%
Exercise	25	92.6%
Diet	24	88.9%
Stress management	22	81.5%
Anxiety management	21	77.8%
Smoking cessation	18	66.7%
Support services	18	66.7%
Environmental health	8	29.6%
Relaxation	3	11.1%
Travel	3	11.1%
Breathing techniques	3	11.1%
Follow on exercise/management programme	2	7.4%
Osteoporosis	1	3.7%
Social services benefits	1	3.7%
Palliative care	1	3.7%
BIPAP	1	3.7%
Goal setting and motivation	1	3.7%
Oxygen	1	3.7%
Inhaler technique	1	3.7%
Dealing with exacerbations	1	3.7%
Sex	1	3.7%
Citizens advice bureau	1	3.7%

The primary educator for the patient self-management education sessions varied across the different teams (Table 2.10). The survey results suggest that a wide variety of healthcare professionals were involved in this process; all services involved physiotherapists and most involved nurses. However, other experts, particularly those from outside health care were less often involved. Peer support was uncommon.

Table 2.10 – PR Self-Management Educators

PR Educator	Frequency	Percentage
Physiotherapist	27	100%
Nurse	23	85.2%
Dietician	20	74.1%
Occupational therapist	15	55.6%
Pharmacist	9	33.3%
Doctor	6	22.2%
Exercise physiologist	5	18.5%
British Lung Foundation	4	14.8%
Psychologist	3	11.1%
Assistant practitioner	3	11.1%
Respiratory support group	2	7.4%
Smoking cessation nurse	2	7.4%
Healthy lifestyles officer	2	7.4%
Physiotherapy assistant/technical instructor	1	3.7%
Smoking cessation, e.g., FagEnds	1	3.7%
Community activity co-ordinator	1	3.7%
Age concern	1	3.7%
Benefits advisor	1	3.7%
Counsellor	1	3.7%
Carers association	1	3.7%
Sports therapist	1	3.7%
Cognitive behavioural therapist	1	3.7%
Community psychiatric nurse	1	3.7%

The services would often involve a number of disciplines in the self-management education aspect of their PR service. Considering the most common four disciplines, eight teams (29.6%) involved a physiotherapist, nurse and dietician, ten teams (37.0%) just had a physiotherapist and eight teams had a physiotherapist and a nurse.

Another aspect of evaluating the self-management strategies utilised across the North West of England was to explore the provision of self-management educational material (see Table 2.11). The results of the survey show that majority of services (25 out of the 27 services surveyed, 92.6%) provided patients with disease specific education material to take away with them. The most common format for the educational material provided for patients was written (96.2%). Other formats included audio or audiovisual formats

and one service with a high proportion of illiterate and non-English speaking ethnic minority patients provided pictorial versions of patient education material (Table 2.12).

Table 2.11– Provision of Educational Material

Provision of Educational Material	Frequency	Percentage
Yes	25	92.6%
No	2	7.4%

Table 2.12 – Format of Educational Material

Format of Educational Material	Frequency	Percentage
Written	25	92.6%
Audio	2	7.4%
Audiovisual	4	14.8%
Pictorial	1	3.7%
Not applicable	2	7.4%

The majority of services assessed self-management knowledge in patients prior to commencing their programme. All 21 PR services (77.8%) that carried out baseline assessment of self-management knowledge also performed routine reassessment of this knowledge at the post intervention stage. Further exploration of the methods used to evaluate patient self-management knowledge revealed a variety of methods (see Table 2.13). Patient feedback was the most frequently used (37.0%), followed closely by the St Georges Respiratory Questionnaire (29.6%). The BCKQ was used by six services.

Table 2.13 – COPD Self-Management Knowledge Assessment Tool

COPD Self-Management Knowledge Assessment Tool	Frequency	Percentage
Patient feedback	10	37.0%
St Georges Respiratory Questionnaire (SGRQ)	8	29.6%
Bristol COPD Knowledge Questionnaire (BCKQ)	6	22.2%
Lung Information Needs Questionnaire (LINQ)	4	14.8%
Chronic Respiratory Questionnaire (CRQ)	1	3.7%
Lung activity daily scale	1	3.7%
Quiz	1	3.7%
Breathing problem questionnaire	1	3.7%
Not applicable	6	22.2%

Of the primary care organisations, two thirds (66.7%) of services formally assessed self-management, while 23.8% of secondary care organisations assessed self-management and all tertiary organisations included self-management assessment as part of routine practice.

2.10 DISCUSSION

2.10.1 Characteristics of PR Programmes in the North West

The results of the survey demonstrated some variation in how PR services were delivered across the North West of England. However, most PR services surveyed were in line with clinical guidance (CSP, 2003; NICE, 2004; NICE, 2010) with regard to length of programme (minimum six weeks) and frequency of attendance (twice a week) and were made up of a Multi-Disciplinary Team (MDT) to deliver the PR intervention. One of these services was the exception to this trend in terms of having no clinical staff involved in the day-to-day running of their programme. This is not supported by current evidence or clinical guidance. Healthcare providers play a critical role in helping patients understand the nature of the disease, potential benefits of treatment, addressing concerns regarding potential adverse effects and events and encouraging patients to develop self-management skills (Bourbeau and Bartlett, 2008). This suggests that, patients attending this programme may not have direct access to a respiratory clinician at the rehabilitation site on a day-to-day basis, therefore self-management skills such as symptom monitoring would be difficult to promote in the target patient population without their vital input/intervention.

In terms of service provision, although there is a significant body of evidence to support the physical benefits of PR for COPD patients, there is also a growing body of evidence on the psychological benefits of patient education and self-management strategies within the same target population. The NICE guidelines (2004, 2010) advocate a PR service that has an exercise or physical training component as well as a patient self-management education component and all 27 services surveyed provided PR programmes comprising of both a self-management education and an exercise component. The BTS (2001) and the CSP (2003) statements on pulmonary rehabilitation state that ease of accessibility to rehabilitation plays an important role in facilitating successful pulmonary rehabilitation; the results of this survey demonstrated that the majority of PR services in the North West were community-based (51.9%) or combination of community and hospital based (40.7%) to improve access to the service. In the most recent Cochrane review of PR for COPD (McCarthy et al., 2015), there was a significant difference in treatment effect with regard to disease-specific health-related quality-of-life, measured using the Chronic Respiratory Questionnaire, across different PR settings. Health-related quality-of-life was higher in hospital-based PR cohorts, compared to community-based cohorts. Although these differences may be attributed to differences in resources or intervention strategies in each setting, comparisons from this meta-analysis were indirect comparisons only and no differences were observed

between both groups when the same outcome (health status) was measured using the St Georges Respiratory Questionnaire. It is important to note that there was also no indication that one questionnaire was more sensitive to change than the other in this case (Griffiths et al., 2000). The vast majority of the services surveyed (96.3%) provided a PR programme for COPD patients on long term oxygen or who were on ambulatory oxygen. This is in line with NICE guidelines from 2004 and updated in 2010 that suggested that even patients requiring supplementary oxygen can benefit from PR and recommend that this patient subgroup within COPD should have access to pulmonary rehabilitation.

There is no standardised duration of programme of pulmonary rehabilitation. Moreover, clinical guidelines from the CSP (2003) and NICE (2004, 2010) recommend six to 12 weeks based on evidence suggesting physiological and behavioural changes have been reflected within that time range. The rehabilitation programme duration also varied across the services surveyed, ranging from a minimum of four weeks to a maximum of 10 weeks in duration. Only one service provided a service that had a programme duration below the recommended six-week rehabilitation period. The other time-related variable that applies to PR programmes is the required frequency of patient attendance: NICE (2004, 2010) recommend two supervised sessions per week. There was little variation in this across the surveyed services with all advising either once or twice a week, but most (82%) required patients to attend supervised PR sessions twice a week as part of their programme. Although there are currently no specific recommendations on the provision of a home exercise programme within PR, clinical guidelines suggest that a home exercise programme is an important component of the rehabilitation process in order to achieve one of the main aims of a rehabilitation programme (CSP, 2003; Barton et al., 2013), i.e., to facilitate or promote lifestyle change as part of the long-term management strategy. The majority of services (92.6%) provided a home exercise programme.

2.10.2 COPD Self-Management Education Strategies

All 27 PR services (100%) surveyed stated that they had a structured self-management education component to their PR programme. However, there was some variety in content across the region. In general, the content of the PR programmes in the North West were consistent with content identified by Bourbeau and Bartlett (2008) as a vital part of encouraging the development of self-management skills by helping patients to understand the nature of the disease, potential benefits of treatment, address concerns regarding potential adverse effects and events. All services covered disease

management (100% of services surveyed), medication and most covered inhaler techniques (96.3%), energy conservation (96.3%), exercise (92.6%), diet (88.9%). Slightly fewer covered stress management (81.5%) and anxiety management (77.8%) as part of the self-management education programmes. Bearing in mind the close association between the development of COPD and cigarette smoking, the relatively high prevalence of smoking in the North West and clinical guidance emphasising the importance of smoking cessation, an unexpected trend that emerged was that only 66.7% of services surveyed specifically addressed smoking cessation as a separate entity. Also surprisingly given the focus on behavioural change and participation in self-management, few services included topics and disciplines, such as psychologists or peer support, which might be important in supporting patients to develop self-management skills.

The format of PR programmes has evolved over time in response to research evidence from a primarily physical training programme with well-established validated objective measures for physical change post-intervention. Although modern PR can be defined as being a multi-component programme, including patient self-management education, it appears that the objective evaluation of relatively newer components of PR such as self-management education is still in the process of being incorporated into practice. Surprisingly, most services surveyed (21 out of the 27 services surveyed or 77.8%) felt that the assessment of patients' COPD self-management based on the definition by Bourbeau (2003) was carried out as part of their programme. Further exploration of the methods used to evaluate patient self-management knowledge revealed variation in the method and objective measures used. At this point it is important to comment on the suitability of the tools and methods used to ascertain whether they are appropriate measures of patient COPD self-management. Out of the 27 services surveyed, 21 (77.8%) used tools that were not considered measures of self-management: ten services (37.0%) reported the use of generic patient feedback which is a subjective tool not measurable on any scale or validated as a measure of self-management. Eight services (29.6%) used the Saint Georges Respiratory Questionnaire (SGRQ), a tool identified by several studies into self-management education as a measure of health status or Health Related Quality-of-life (HRQoL) and not a measure of self-management (Monninkhof et al., 2003; McGeoch et al., 2006; Efraimsson et al., 2008; Khdour et al., 2009). The domains of the SGRQ do not address specific issues pertinent to the demonstration of self-management such as self-efficacy with medication or during an exacerbation. This suggests that it is therefore unlikely to be validated as a measure of self-management, whereas, it has been shown to be sensitive to change in health status

(Griffiths et al., 2000). One service (3.7%) used the Chronic Respiratory Questionnaire (CRQ) which is designed to measure health status (Williams et al., 2001), another service (3.7%) used the Lung Activity Daily Scale to assess patients' knowledge, designed to assess the impact on patients' activities of daily living and one service (3.7%) used the Breathing Problem Questionnaire which is also described as a measure of Quality-of-life (Hyland et al., 1994). These findings suggest that there is a lack of clarity about what self-management is as a concept among the clinicians who are responsible for encouraging patients to develop self-management skills. This has implications for clinical practice. This is consistent with academic research, which acknowledges that the growing body of evidence regarding the concept self-management is still unclear and contradictory (Monninkhof et al., 2003; Effing et al., 2007; Harris et al., 2008; Effing et al., 2009; Zwerink et al., 2014 and Lenferink et al., 2017). Further research is required to clarify issues regarding the constituents of self-management, forms of self-management intervention strategies, optimal duration of self-management programmes with sufficient time to effect behavioural change, optimal intervention stage(s), appropriate measures of self-management and appropriate timing of evaluation.

2.10.3 Liverpool Pulmonary Rehabilitation Programme

In the main, the Liverpool PR programme is very similar to other services. It is provided in both hospital and community settings and there was a fairly even split of these settings in the region. Like most PR services, it includes a chest physiotherapist and is multidisciplinary. Perhaps though it is more comprehensive than many of the other services as it involves input from a greater range of health professionals and includes support workers and smoking cessation. Like most of the services, the Liverpool PR service provides a hospital-based clinic for patients on oxygen.

Like all the other PR programmes, the Liverpool programme includes both an exercise and a self-management component, albeit again the self-management component appears to be more comprehensive in the range of topics covered, as it includes smoking cessation. It has a similar duration to most of the other programmes, but offers only one supervised session per week while most of the others offer two. This deviation from the clinical guidance is due to concerns about high attrition rates with a twice-weekly service format, patient feedback with regards to an increased burden on patients having to attend twice weekly sessions and due to limited resources, such as financial costs relating to additional venue rental costs with a bi-weekly programme and staffing limitations.

Like most services, self-management is assessed pre and post PR. The use of the BCKQ was not the most commonly used method of assessment among the other services as only 6 in total used this measure, but the BCKQ appears to be one of the most pertinent of the methods used to directly measure change in self-management knowledge and skills, as other methods were either not validated or measures of health-related quality-of-life or activities of daily living.

2.10.4 Strengths and Limitations

A strength of the study was in having the survey administered by the same person to optimise the consistency with which the questions were asked. The 100% response rate for the survey can also be considered a strength of the survey and suggests that the questions were understandable and relevant to participants (McColl et al., 2001). Limitations of the survey included the risk of bias from the researcher being the person to administer the survey, although the use of first choice response from participants and the use of focus groups during the development of the questionnaire to ensure a well-designed questionnaire, potentially limits the ability to introduce bias (Smith and Noble, 2014). Another potential limitation of this study may be the closed question format of the survey questionnaire, as it could not explore clinicians understanding of self-management within their services. The use of open-ended questions or a mixture of close and open-ended questions as follow-up questions could have enabled the research student to gain a greater understanding of the PR services that were being delivered in the region. These follow-up questions would have enabled the provision of details of why the service was designed as it was, what they felt constituted an optimal service and why, and their experiences of delivering the service: However, these formats can be more time consuming and place a higher burden on the study participant (Kelley et al., 2003). Therefore, a close-end format was chosen as it reduced the burden on the survey participants who were busy clinicians and may have been less inclined to participate in a lengthy, time-consuming survey. As this survey was exploratory in nature and the questions had been developed using focus groups, it was felt that the data obtained using salient questions would meet the objectives for the survey (McColl et al., 2001). Another possible limitation was restricting the survey to one region, as the North West may not be representative of the national picture and regional differences such as service level agreements or local practice policies, may influence the responses from the clinicians. However, due to limited resources, the research student had to assess the practicality of being able to obtain usable data from all 152 PCTs in England in the time available to carry out the survey and weigh this up against the benefits of a higher response rate with potentially higher quality data from a smaller sample size. The

decision was made to opt for a smaller sample size as this was an achievable in the timescale for the programme of study.

2.11 CONCLUSION

In terms of PR service characteristics, the results of the survey of 27 PR services across the North West of England showed that all PR services incorporated self-management education and an individually-tailored exercise programme into their PR programme similar to the Liverpool PR service. Although there were variations in the structure of PR services and the assessment, delivery and evaluation of the effect of self-management education across the region, these were mainly consistent with clinical guidance and the self-management education strategy adopted by the Liverpool PR service. An important finding was with regard to the methods used to evaluate the effect of the self-management, only 10 services (37.0%) utilised a validated measure of self-management.

Overall, the variety in the methods or formats of self-management education and its evaluation across the North West of England demonstrated an awareness of the importance of self-management in the successful delivery of a comprehensive PR programme and quality COPD patient care. Although the approaches within these services were different, there were several themes in common between the different services. Most services had a standardised approach to their method of assessment, delivery of the intervention and re-evaluation of patients attending pulmonary rehabilitation. The Liverpool PR programme and the self-management education strategy was typical of the approach used across other PR services in the North West of England, suggesting that any interpretation of data obtained from this service may be generalisable to the wider COPD and PR population. In the next chapter, retrospective analysis of routinely collected outcomes data from patients attending the Liverpool PR programme will be carried out to explore the impact of the Liverpool PR self-management education strategy on health outcomes for COPD patients.

CHAPTER THREE

A RETROSPECTIVE ANALYSIS OF AN ADMINISTRATIVE DATABASE OF PATIENTS REFERRED FOR ASSESSMENT FOR A PULMONARY REHABILITATION PROGRAMME

3.1 INTRODUCTION

In the previous chapter, how self-management education is incorporated into PR was explored using a survey questionnaire to collect information on service structure, constituents of PR, content of self-management education strategy and how the treatment effect of this strategy is measured in PR services across the North West of England. This survey showed that all the services surveyed include some form of self-management education into their PR programme and the format of this varied in content and delivery, but was mainly in accordance with clinical guidance. The main difference was in the evaluation of self-management, which differed considerably between services in terms of the measurement of self-management. The findings of the survey also demonstrated that the Liverpool PR service was not atypical of the COPD self-management education strategy used in the region suggesting that findings from analysis of data from this service may be generalisable to the wider COPD and PR populations. The Liverpool PR service holds an administrative database. Data is routinely collected on patient outcomes, including a self-management measure (BCKQ). Data is collected at baseline before PR, after PR is completed and three months later. This chapter reports on a retrospective analysis of this PR data to explore the impact of self-management on a cohort of COPD patients attending the Liverpool PR service. The implications for a prospective study for further study of self-management and health outcome measures, implications for practice and implications for research are discussed.

3.2 REFLECTION ON THE RESEARCH JOURNEY

At the beginning of this programme of study, I was certain I understood the concept of self-management in the COPD population, I was an experienced clinician and was up to date on the most current intervention strategies for COPD patients. However, what I had discovered was that, over time, the concept of self-management had evolved from a uni-dimensional approach to patient education to a complex, multi-faceted clinical management strategy that was yet to be defined and yet to have an established body of evidence to support it, especially in PR. The changing scope of self-management, a relatively new and small body of evidence on self-management for COPD patients, as well as, a lack of a concurrent evidence base for self-management for COPD made it

difficult for researchers to make recommendations for practice, meaning that clinicians like myself lacked insight into its application in COPD care and its relevance in PR. An example of this is reflected in this research journey, as I observed a marked difference in the measures used to assess self-management in the survey of PR services across the North West of England. I came to the realisation that as a clinician, I and my colleagues would benefit from better understanding and insight into the concept of self-management and self-management education in order to begin to understand implications for practice and/or research.

3.3 METHODOLOGICAL APPROACH

Two of the thesis objectives were to:

- explore the impact of a self-management education strategy on health outcomes.
- explore the relationship between self-management outcomes within a PR programme and functional capacity, respiratory disability and emotional functioning.

To meet these objectives, a mainly quantitative research approach was adopted: Quantitative research is an approach for testing objective theories by examining the relationship among variables (Creswell, 2014). Aliaga and Gunderson (2000) describe the quantitative research approach as explaining phenomena by collecting numerical data that are analysed using mathematically based methods. Quantitative research often translates into the use of statistical analysis to make the connection between what is known and what can be learned by research. Consequently, analysing data with quantitative strategies requires an understanding of the relationships between variables by either descriptive or inferential statistics (Trochim, 2000). This approach was deemed the most suitable approach for this study, as the research student required the ability to collect information in a structured way and the ability to compare the data collected as part of the process of understanding the concept of self-management incorporated into PR as part of the management of COPD.

There were two options available to the research student, either design a prospective study to collect data on the health outcomes routinely used in practice or review already collected data, from the Liverpool PR service's outcomes database. Reviewing the information already collected on outcome measures used to evaluate the incorporation of self-management in the Liverpool PR service would enable the research student to:

1. Start to understand how this intervention was working in practice in terms of the effect of the intervention on self-management and health outcomes
2. Identify any relationships between different variables, characterise the patient cohort
3. Identify any relationships between the cohort characteristics and health outcomes or changes in self-management and health outcomes
4. Identify any flaws or gaps to inform the design of a prospective study.

Therefore an evaluation of the Liverpool PR outcomes database was chosen as the next step, as the information had already been collated and was thought to provide sufficient coverage to enable the research student to make comparisons between pre-intervention and post intervention variables and ascertain the relationships between these variables. A particularly useful application for a retrospective study is as a pilot or exploratory study in anticipation of a prospective study (Hess, 2004). This means that the findings from the retrospective analysis of health outcomes data from the Liverpool PR database, may be useful to inform the design of prospective designs as well as provide insight to how the service worked in practice. Due to the limited timeframe of the programme of study and the limited resources available to a lone research student, the use of data that was already available was deemed not only to be to be prudent but an efficient use of the available resources (Hess, 2004) to explore the impact of the Liverpool PR approach on self-management and health outcomes.

3.4 AIMS AND OBJECTIVES

The purpose of this study was to understand the role of self-management education as part of PR for patients with COPD. The study objectives were to:

1. Provide a detailed characterisation of the patient cohort attending the Liverpool PR programme.
2. Ascertain trends in patient self-management knowledge as measured by the BCKQ prior to commencing, at the end of and follow-up after the PR programme.
3. Explore the inter-relationships between changes in self-management knowledge and changes in functional ability, changes in respiratory disability and changes in emotional functioning.

3.5 METHODS

3.5.1 Study Design

This study is a retrospective analysis of anonymised patient data extracted from a clinical database (the PR health outcomes database) held by the PR service at the Liverpool Heart and Chest Hospital. The PR database is an administrative database of clinical information, including, patient demographic information, disease category information, smoking status and objective measures of disease self-management education, functional capacity measures, anxiety levels and depression levels measured at set time intervals, i.e., at baseline, on completing the programme and three months after completing the programme (see Figure 3.1). The database was initially set up to record health outcomes data to support routine reports for the commissioners of the service. Data on patient referrals and some patient demographic information is extracted from the hospital Patient Administrations Systems (PAS) database and additional data on clinical characteristics such as disease severity, symptoms and symptom severity is collected by assessing clinicians on patient visits and is inputted into the PR database by PR administrative staff.

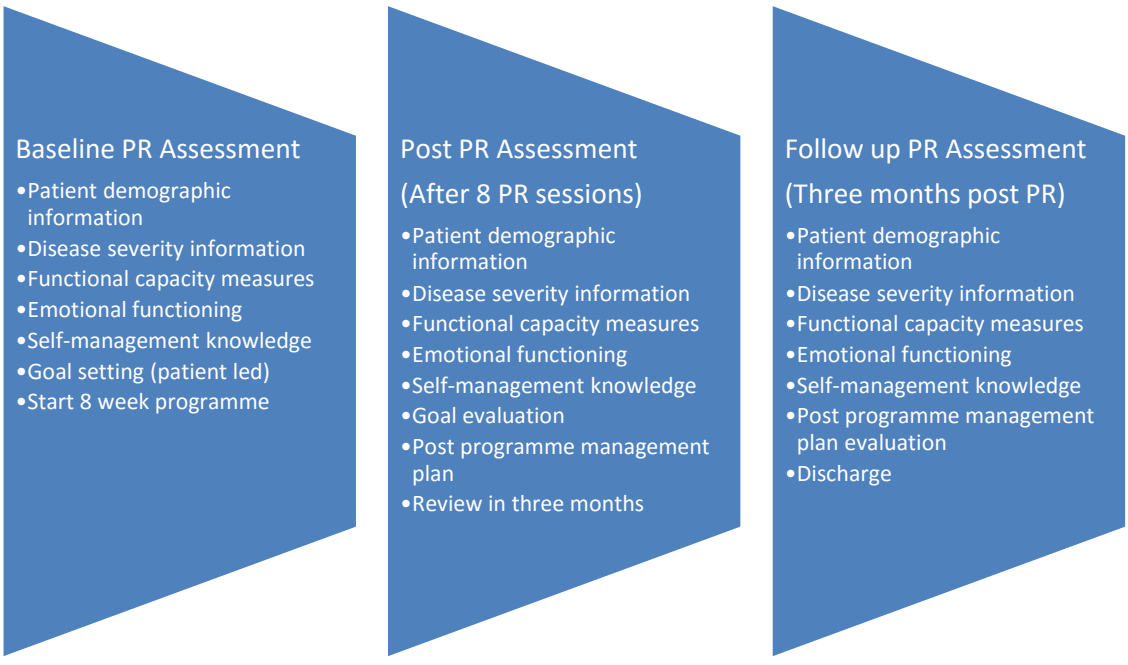

Figure 3.1 – Summary PR Service Model (PR Data)

The research student received permission from the Liverpool Heart and Chest Hospital NHS Foundation Trust to have full access to the PR database for the purpose of this study (see Appendices 16 and 17 for the NHS Trust permission and access letters).

3.5.2 Setting

The data was collected from patients attending one hospital and five community based clinics within Anfield, Norris Green, Broadgreen, Toxteth, Allerton and the Liverpool Heart and Chest Hospital. These clinics were run by the PR team based at the Liverpool Heart and Chest Hospital.

3.5.3 Participants

The research student carried out a data search for all new COPD patients registered on the PR database between 01/01/2009 until 30/06/2011 (inclusive) on the 30/06/2011. These dates were chosen because patient assessment using the BCKQ as a measure of self-management was introduced on the 01/01/2009. Patients were included in the study if they attended for the PR baseline assessment. Patients were excluded if they were medically unstable as these patients were not suitable for PR. Non-COPD patients undergoing pulmonary rehabilitation, e.g., Bronchiectatic patients, post lung surgery or hyperventilation syndrome patients were excluded from this study because of the lack of evidence on the efficacy of PR for these patients.

3.5.4 Sample Size

There were 554 eligible patients registered between 01/01/2009 and 30/11/2011 with data recorded on the database.

3.5.5 Data Collection and Data Protection

The normal procedure for this PR programme was that all routine data collated during patient assessment sessions was recorded on a password protected electronic database at the Liverpool Heart and Chest Hospital. The retrospective study involved the extraction of the following routinely collected data from the PR database for analysis:

- Patient demographic information, i.e., age, sex, first part of residential postcode, smoking status
- Clinical characteristics, i.e., COPD self-management education measure, disease category, functional capacity measure, respiratory disability and measure of emotional functioning

The data extracted from the main database was stored in a separate password protected file on the Liverpool Heart and Chest Hospital server. Any patient identifiable data was removed or modified by transformation (e.g. age to replace date of birth) by the research student in order to anonymise the data for the study, and to maintain patient confidentiality, prior to extraction onto an Excel spreadsheet. The Excel data

spreadsheet was transferred via an encrypted pen drive to the student's password protected space on the University of Central Lancashire server, as required for analysis.

3.5.6 Data Analysis

Patient characteristics were described using frequencies and proportions or means, medians, with interquartile range and standard deviations, as appropriate. Patient attrition and retention rates were estimated using data on attendance at baseline assessment and completion of the PR programme. Baseline levels of self-management education (BCKQ score), functional capacity (SWT), respiratory disability (MRC dyspnoea scale) and emotional functioning (HADS) were analysed in conjunction with the levels assessed on completing the programme and then the data for three months post completion of the PR programme.

Changes in the outcomes measures were compared using paired t-tests for interval data or chi-squared tests for categorical data. Each variable was also evaluated at each time point to ascertain correlations between the outcome measures at each time point and correlations between changes from baseline at each point in time. Initially, scatterplots or boxplots of relationships between variables were drawn and the strength of any pairwise relationships was then assessed by computing a Pearson Correlation Coefficient for apparently linear relationships, Spearman's Correlation Coefficient for non-interval data or Kendall Tau-b for ordinal data. The strength of the correlation (r) was determined using the guide on absolute value of r by Evans (1996) in Table 3.1.

Table 3.1 – Strength of Correlation (Evans, 1996)

r	Strength of Correlation
0.00 – 0.19	Very weak
0.20 – 0.39	Weak
0.40 – 0.59	Moderate
0.60 – 0.79	Strong
0.80 – 1.00	Very strong

3.5.7 Ethical Considerations

The main ethical considerations for this study were with regard to accessing routinely collected PR patient data stored on the PR database for research purposes and maintaining patient confidentiality during the data extraction, data storage and data analysis processes.

Approvals

Permission was gained from the Liverpool Heart and Chest Hospital NHS Foundation Trust to use the information recorded on the PR database and to store anonymised data on a separate database which could be accessed for review purposes by the supervisory team from the University of Central Lancashire (see Appendices 16 and 17). Confirmation that no NHS ethics approval was required for the purpose of this study was also obtained from the Trust's Research department (see Appendix 18). Ethics approval was gained from the University of Central Lancashire (see Appendix 19).

Data governance

All patient information used was anonymised by removing identifiers and transforming dates to ensure that patient confidentiality was maintained throughout and the anonymisation or transformation of patient identifiable information enabled the research student to use the data for the purpose of this study, without requiring individual patient consent. All primary data will be stored for a minimum of five years after the completion of the project as per the University of Central Lancashire's code of conduct for research and will be destroyed once the full retention period has expired as per the University of Central Lancashire's protocol.

3.6 RESULTS

The total number of patients extracted from the database for the study period was 1926 of whom 1509 patients met the criteria for the study. Of these, 875 (58.0%) patients attended for baseline assessment. A further fifty patients out of these 875 were excluded from the study as they were deemed medically unstable and therefore not able to participate in the programme (see Figure 3.2 for the Study Flowchart).

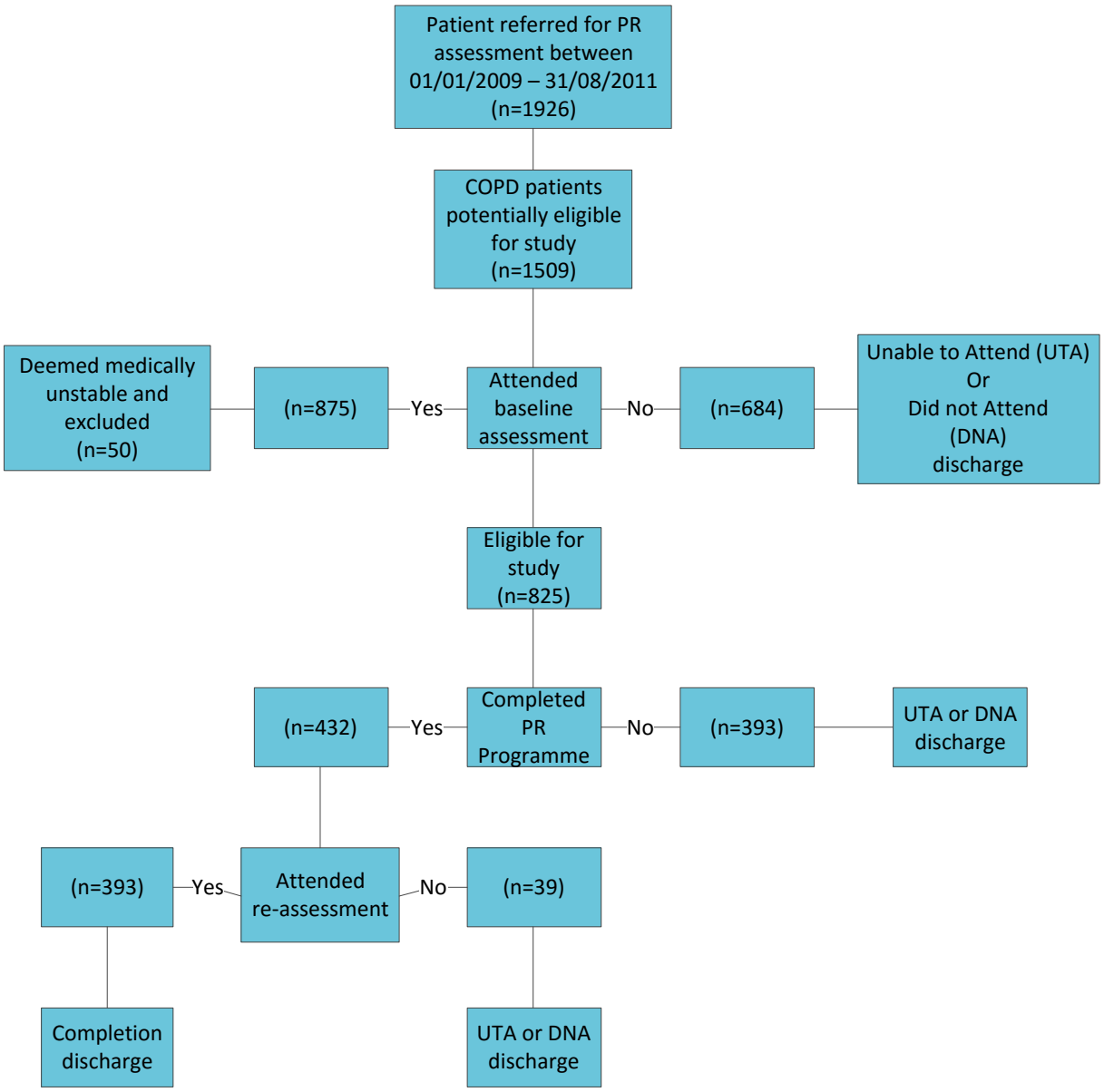

Figure 3.2 – Retrospective Study Flowchart

3.6.1 Baseline Patient Demographic and Clinical Characteristics

Comparison of baseline characteristics in attenders and non-attenders

There were 825 participants who attended the baseline assessment and were suitable for PR. The baseline characteristics of those who attended the baseline assessment and found to be suitable (n=825) and those that did not attend (n=684) are described in Table 3.2.

The mean age was 66 years old and the cohort was predominantly female (n=865, 57.4%). Most were categorised as having mild COPD based on FEV1 (n=520, 46.7%), were from the most socioeconomically deprived area(s) of Liverpool (n=453, 30%) and were ex-smokers (n=575, 41.4%).

Comparisons of the baseline characteristics of those who attended the baseline and those who did not attend suggested that those who did not attend were more likely to be younger (64 years vs 67 years, t=-4.4, df=1504, p=<0.001), came from the most deprived parts of the city (x^2=37.5, p=<0.001) and were still smoking (x^2=47.5, p=<0.001). The results showed there was no significant difference in the gender distribution between the group that attended their baseline assessment and those that did not (x^2=0.15, p=0.70).

Table 3.2 – Baseline Patient Demographic Information

	FULL DATASET (n = 1509)	ATTENDED BASELINE ASSESSMENT (n = 825)	DID NOT ATTEND BASELINE ASSESSMENT (n = 684)
AGE			
Mean	65.6	66.6	64.1
SD	10.6	10.3	10.8
Min	27	27	37
Max	93	92	93
Missing	3	3	0
SEX			
Female	865 (57.4%)	469 (56.9%)	396 (57.9%)
Male	643 (42.6%)	355 (43.1%)	288 (42.1%)
Missing	1	1	0
SOCIOECONOMIC QUINTILE			
1 (most deprived)	453 (30.0%)	202 (24.5%)	251 (36.7%)
2	344 (22.8%)	189 (22.9%)	155 (22.7%)
3	281 (18.6%)	158 (19.2%)	123 (18.0%)
4	252 (16.7%)	152 (18.4%)	100 (14.6%)
5 (least deprived)	179 (11.9%)	124 (15.0%)	55 (8.0%)
Missing	0	0	0
DIAGNOSIS			
COPD	1469 (97.3%)	800 (97.0%)	669 (97.8%)
COPD/Bronchiectasis	21 (1.4%)	13 (1.6%)	8 (1.2%)
COPD/Asthma	19 (1.3%)	12 (1.5%)	7 (1.0%)
Missing	0	0	0
SMOKING STATUS			
Current	505 (36.4%)	230 (30.9%)	275 (42.8%)
Ex-smoker	575 (41.4%)	367 (49.3%)	208 (32.3%)
Non-smoker/Never smoked	70 (5.1%)	40 (5.3%)	30 (4.7%)
Not declared	238 (17.1%)	108 (14.5%)	130 (20.2%)
Missing	121	80	41
FEV1 RATING			
Normal	174 (15.6%)	112 (18.2%)	62 (12.5%)
Mild	520 (46.7%)	283 (45.9%)	237 (47.7%)
Moderate	324 (29.1%)	172 (27.9%)	152 (30.6%)
Severe	96 (8.6%)	50 (6.1%)	46 (9.3%)
Missing	395	208	187
REFERRAL SOURCE			
Nurse	692 (46.0%)	377 (45.9%)	315 (46.1%)
Consultant	102 (6.8%)	63 (7.7%)	39 (5.7%)
Matron	89 (5.9%)	44 (5.4%)	45 (6.6%)
GP	247 (16.4%)	146 (17.8%)	101 (14.8%)
Physio	48 (3.2%)	26 (3.2%)	22 (3.2%)
Medicines Management Team	326 (21.7%)	165 (20.1%)	161 (23.6%)
Missing	5	4	1
REFERRING ORGANISATION			
Primary Care	1277 (85.0%)	695 (84.9%)	582 (85.2%)
Tertiary Care	112 (7.5%)	68 (8.3%)	44 (6.4%)
Secondary Care	113 (7.5%)	56 (6.8%)	57 (8.3%)
Missing	7	6	1
YEAR			
2009	226 (15.0%)	93 (11.3%)	133 (19.4%)
2010	702 (46.5%)	259 (31.4%)	443 (64.8%)
2011	581 (38.5%)	473 (57.3%)	108 (15.8%)
Missing	0	0	0

Comparison of baseline characteristics in patients who attended reassessments and follow up with those that did not

Only 432 patients (49.4%) out of the 825 patients assessed and eligible for the study completed the programme and attended their post PR assessment, and 393 patients (47.6%) attended follow up. The demographic characteristics of the groups who commenced the rehabilitation programme and then did or did not attend their reassessment or follow up assessments are described in Table 3.3.

The baseline median SWT in those that attended the reassessment was higher than in those who did not attend their reassessment compared to those that did not and was higher in those who attended follow up compared to those that did not. This suggests that that the functional capacity of patients that did not attend their assessments was lower at baseline than those who attended their assessments. Overall, there were significantly more severely breathless patients in the groups that did not attend their reassessment or follow up compared to the groups that did (x^2=10.05, p=0.04). Fewest MRC Grade 5 patients occurred in the group that attended all three assessment points (n=104, 26.7%) followed by those who attended two out of the three assessment points (n=116, 27.0%) and those who attended one (n=229, 28.2%).

The mean HADS A and D scores were worse in the groups that did not attend reassessment compared to those that did, and in those that did not attend follow up compared to those that did. This pattern was consistent across both components measures. Patients with higher anxiety and depression scores and therefore worse levels of psycho-emotional function were less likely to be reassessed than patients with lower levels of anxiety and depression who did (Anxiety t=2.8, df=865, p=0.005 and Depression t=2.7, df=866, p=0.019).

The overall results showed a significantly lower baseline level of knowledge in the patients who did not attend their assessments when compared to those who attended as indicated by the mean BCKQ scores in Table 3.3.

Table 3.3 – Baseline Clinical Information

		ATTENDED BASELINE ASSESSMENT (n = 825)	ATTENDED REASSESSMENT (n = 432)	DID NOT ATTEND REASSESSMENT (n = 393)	ATTENDED FOLLOW UP (n = 393)	DID NOT ATTEND FOLLOW UP (n = 39)
SWT*						
Median		177.3	160.0	130.0	160.0	120.0
Percentiles	25	80.0	90.0	70.0	90.0	90.0
	50	140.0	160.0	130.0	160.0	120.0
	75	250.0	250.0	240.0	250.0	220.0
Min		0	20	0	20	30
Max		750	750	630	750	590
Missing		1	0	1	0	0
MRC**						
1		32 (3.9%)	24 (5.6%)	8 (2.1%)	22 (5.6%)	2 (5.1%)
2		125 (15.4%)	79 (18.4%)	46 (12.0%)	71 (18.2%)	8 (20.5%)
3		216 (26.6%)	116 (27.0%)	100 (26.2%)	105 (26.9%)	11 (28.2%)
4		209 (25.8%)	94 (21.9%)	115 (30.1%)	88 (22.6%)	6 (15.4%)
5		229 (28.2%)	116 (27.0%)	113 (29.6%)	104 (26.7%)	12 (30.8%)
Missing		14	3	11	3	0
HADS A***						
Mean		8.9	7.9	9.9	7.9	8.5
SD		4.9	4.7	5.0	4.7	5.1
Min		0	0	0	0	0
Max		21	21	21	21	21
Missing		7	2	5	2	0
HADS D****						
Mean		7.3	6.7	8.0	6.6	7.0
SD		4.2	4.0	4.4	4.0	3.6
Min		0	0	0	0	1
Max		21	20	21	20	16
Missing		7	0	7	0	0
BCKQ*****						
Mean		29.2	29.8	28.5	29.9	28.6
SD		11.0	10.5	11.4	10.5	10.8
Min		0	0	0	0	0
Max		65	65	65	65	50
Missing		1	0	1	0	0

*SWT – Min=0, Max=1020, Direction of change – higher score denotes improvement

**MRC – Min=1, Max=5, Direction of change – higher score denotes deterioration

***HADS A – Min=0, Max=21, Direction of change - higher score denotes deterioration

****HADS D – Min=0, Max=21, Direction of change - higher score denotes deterioration

**** BCKQ – Min=0, Max=65, Direction of change - higher score denotes improvement

3.6.2 Self-Management

Further analysis of changes to the BCKQ at completion of PR (reassessment) and at follow up three months later was limited to the 393 participants who completed all three assessments (see Table 3.4). There was a statistically significant 21.1% relative increase in mean BCKQ score from baseline to post-intervention (difference in mean score from baseline = 8, paired t test =-15.154, df=392, $p<0.001$) which, although not maintained at the same level on re-evaluation three months later, was still statistically significant (difference in mean BCKQ score from baseline = 7, paired t test =-13.654, df=392, $p<0.001$).

Table 3.4 – Bristol COPD Knowledge (BCKQ*) Outcomes

n = 393	Baseline BCKQ	Reassessment BCKQ	Follow Up BCKQ
Mean	29.9	37.9	36.9
SD	10.5	9.2	10.5
Min	0	0	0
Max	65	65	65
Missing	0	0	0

* BCKQ – Min=0, Max=65, Direction of change - higher score denotes improvement

Trends in mean BCKQ within subgroups (attenders and non-attenders) of the study were also analysed (see Table 3.5). The results demonstrated that patients who attended their baseline and post-intervention assessments but did not attend their follow-up had a lower mean post-intervention BCKQ score (28.5) when compared to those that attended all three assessments with a mean BCKQ score of 29.9 (t=-2.864, df=431, p=0.004).

Table 3.5 – Bristol COPD Knowledge – BCKQ* Outcomes (Subgroups)

	ATTENDED BASELINE ASSESSMENT (n = 825)	ATTENDED RE-ASSESSMENT (n = 432)	DID NOT ATTEND RE-ASSESSMENT (n = 393)	ATTENDED FOLLOW UP ASSESSMENT (n = 393)	DID NOT ATTEND FOLLOW UP ASSESSMENT (n = 39)
BASELINE BCKQ					
Mean	29.2	29.8	28.5	29.9	28.6
SD	11.0	10.5	11.4	10.5	10.8
Min	0	0	0	0	0
Max	65	65	65	65	50
Missing	1	0	1	0	0
REASSESSMENT BCKQ					
Mean	N/A	37.5	N/A	37.9	33.3
SD		9.5		9.2	11.0
Min		0		0	0
Max		65		65	49
Missing		0		0	0
FOLLOW UP BCKQ					
Mean	N/A	N/A	N/A	36.9	N/A
SD				10.5	
Min				0	
Max				65	
Missing				0	

* BCKQ – Min=0, Max=65, Direction of change - higher score denotes improvement

The analysis showed a positive moderate correlation between baseline BCKQ scores and post-intervention BCKQ scores (Pearsons r=0.439, p<0.001) (see Figure 3.3) and baseline BCKQ scores and follow up BCKQ scores (Pearsons r=0.527, p<0.001) (see Figure 3.4). There was also a strong negative correlation between baseline BCKQ scores and the changes from baseline BCKQ score at the post-intervention stage (Pearsons r=-0.616, p<0.001) (Figure 3.5), and a moderate negative correlation (Figure 3.6) between

baseline BCKQ scores and the change from baseline in BCKQ scores at the three month post completion follow-up stage (Pearsons r=-0.487, p<0.001).

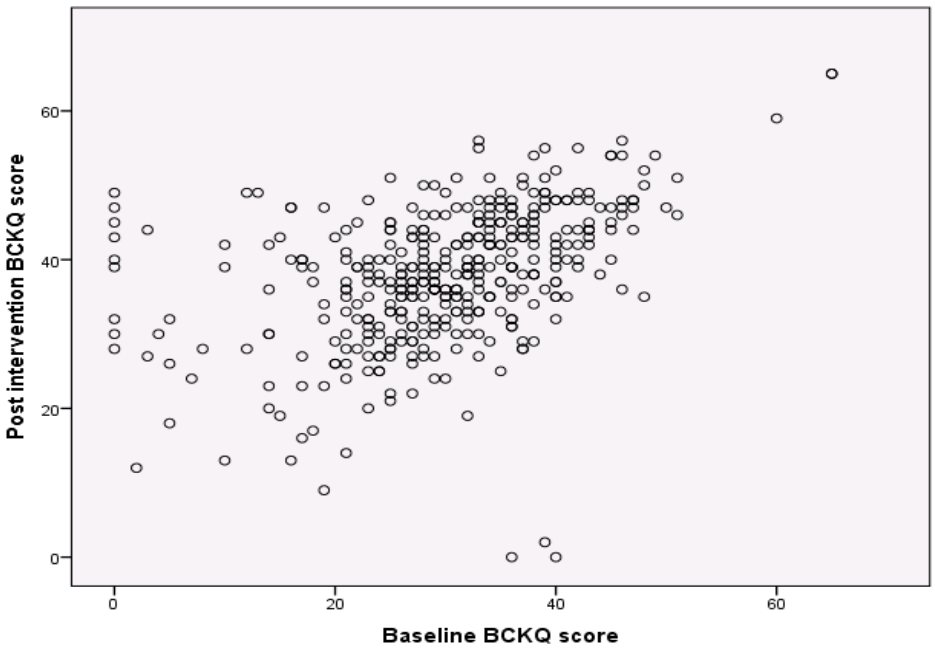

Figure 3.3 – Scatterplot of baseline and reassessment self-management knowledge

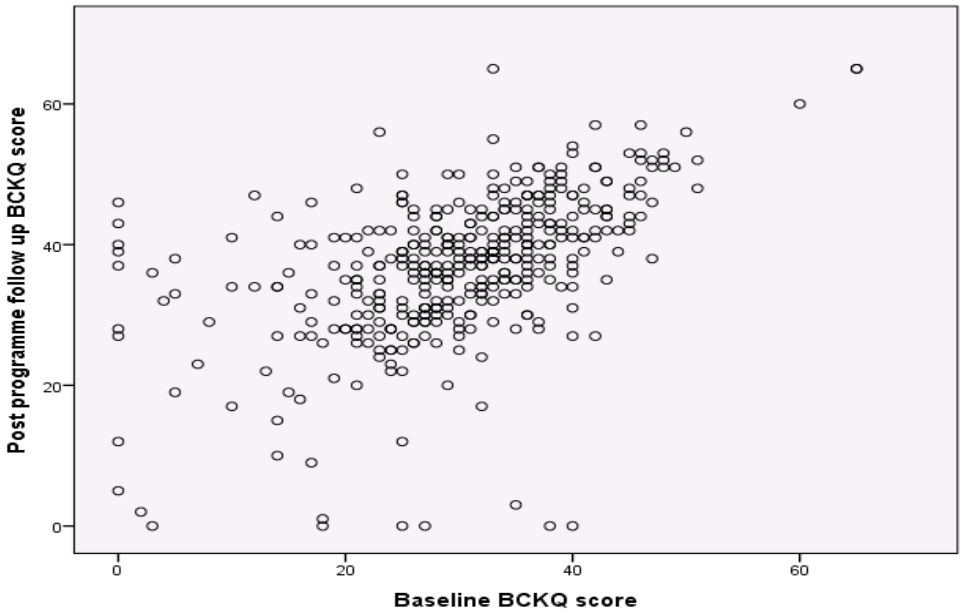

Figure 3.4 – Scatterplot of baseline and follow up PR self-management knowledge

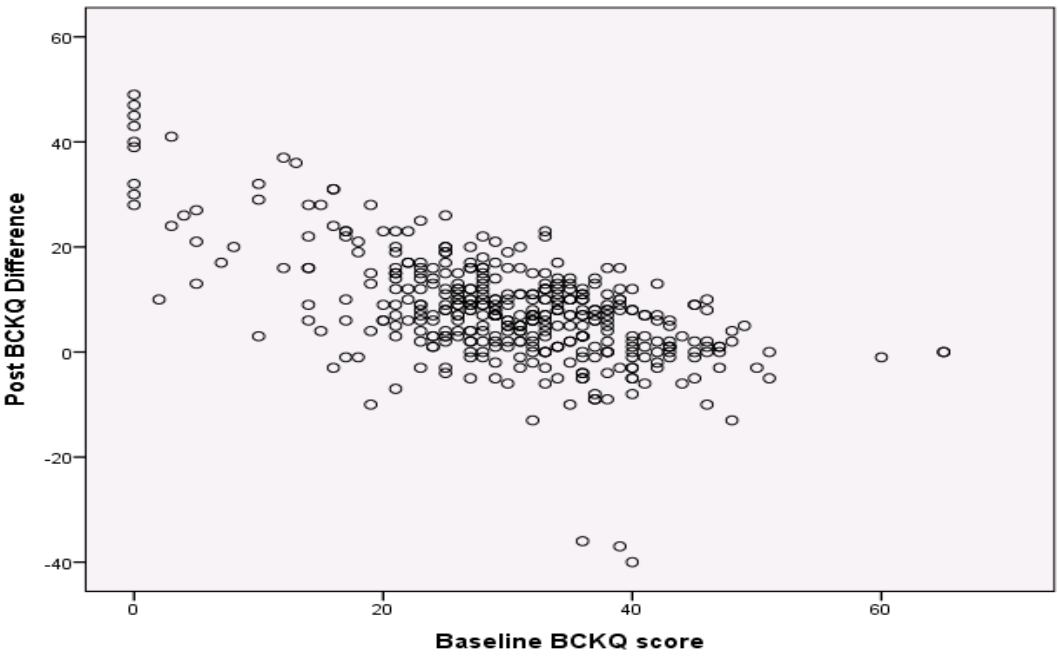

Figure 3.5 – Scatterplot of baseline and reassessment changes in self-management knowledge

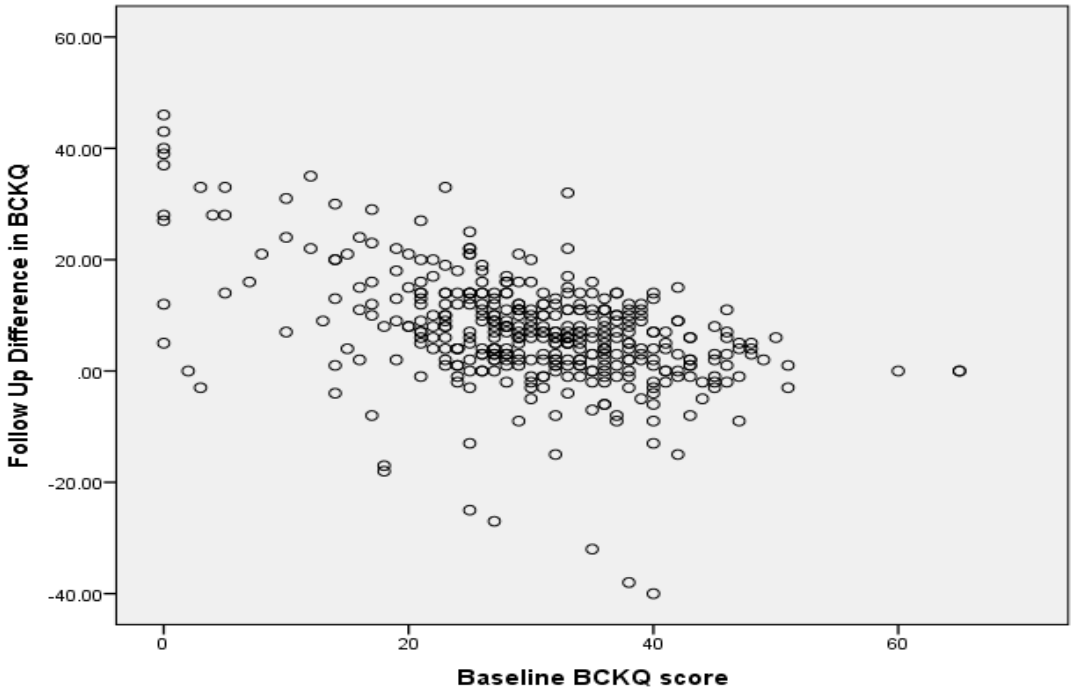

Figure 3.6 – Scatterplot of baseline and follow up changes in self-management knowledge

3.6.3 Inter-relationships between changes in knowledge and changes in functional ability and changes in emotional functioning

Functional Capacity

The overall trend (see Table 3.6) across all the datasets reflected an improvement of 40m (25.0%) in median distance walked between baseline and post-intervention assessment stages ($p<0.001$) which, is maintained from the post intervention stage to the at the follow up stage three months later ($p=0.007$) and still improved compared to baseline ($p<0.001$).

Table 3.6 – Functional Capacity (SWT*)

n = 393	Baseline SWT	Reassessment SWT	Follow Up SWT
Median	160.0	200.0	200.0
Mean	177.3	235.5	226.4
Percentile:			
25	90.0	140.0	120.0
50	160.0	200.0	200.0
75	250.0	330.0	300.0
Min	20	30	0
Max	750	840	1020
Missing	0	7	18

*SWT – Min=0, Max=1020, Direction of change – higher score denotes improvement

Respiratory Disability

The overall trend (Table 3.7) demonstrated a migration of participants from the more severe MRC grades to less severe grades post-intervention, suggesting an improvement in respiratory disability ($x2=534.9$, $df=16$, $p<0.001$). The emerging trend at the follow up stage is a maintained improvement compared to baseline ($x2=339.9$, $df=16$, $p<0.001$).

Table 3.7 – Respiratory Disability (MRC*)

n = 393	Baseline MRC	Reassessment MRC	Follow Up MRC
1	22 (5.6%)	30 (7.7%)	36 (9.2%)
2	71 (18.2%)	106 (27.0%)	94 (24.0%)
3	105 (26.9%)	133 (33.9%)	126 (32.1%)
4	88 (22.6%)	74 (18.9%)	63 (16.1%)
5	104 (26.7%)	49 (12.5%)	73 (18.6%)
Missing	3	1	1

*MRC – Min=1, Max=5, Direction of change – higher score denotes deterioration

Emotional Functioning

There was a statistically significant improvement in anxiety post-intervention of 0.4 points (5.3%, t=4.369, df=430, p<0.001) and a further improvement of 0.3 points (4.2%) at the follow up stage three months later (t=4.884, df=389, p<0.001) (see Table 3.8).

Table 3.8 – HADS Anxiety (HADS A*)

n = 393	Baseline HADS A	Reassessment HADS A	Follow Up HADS A
Mean	7.9	7.5	7.2
SD	4.7	4.8	4.7
Min	0	0	0
Max	21	21	21
Missing	2	2	2

*HADS A – Min=0, Max=21, Direction of change - higher score denotes deterioration

The overall trend for depression was an improvement in depression post-intervention of 0.3 points (5.0%, t=5.168, df=433, p<0.001) which is maintained at the follow up stage three months later (t=4.118, df=391, p<0.001) (see Table 3.9).

Table 3.9 – HADS Depression (HADS D*)

n = 393	Baseline HADS D	Reassessment HADS D	Follow Up HADS D
Mean	6.3	6.0	6.0
SD	4.0	3.8	3.9
Min	0	0	0
Max	20	17	21
Missing	0	1	2

*HADS D – Min=0, Max=21, Direction of change - higher score denotes deterioration

3.6.4 Relationships between self-management knowledge, functional capacity and emotional functioning

The results indicated a strong positive correlation (see Figure 3.7) between change from baseline in BCKQ score at the post intervention stage and change from baseline in BCKQ at the follow-up stage (Pearsons r=0.619, p<0.001).

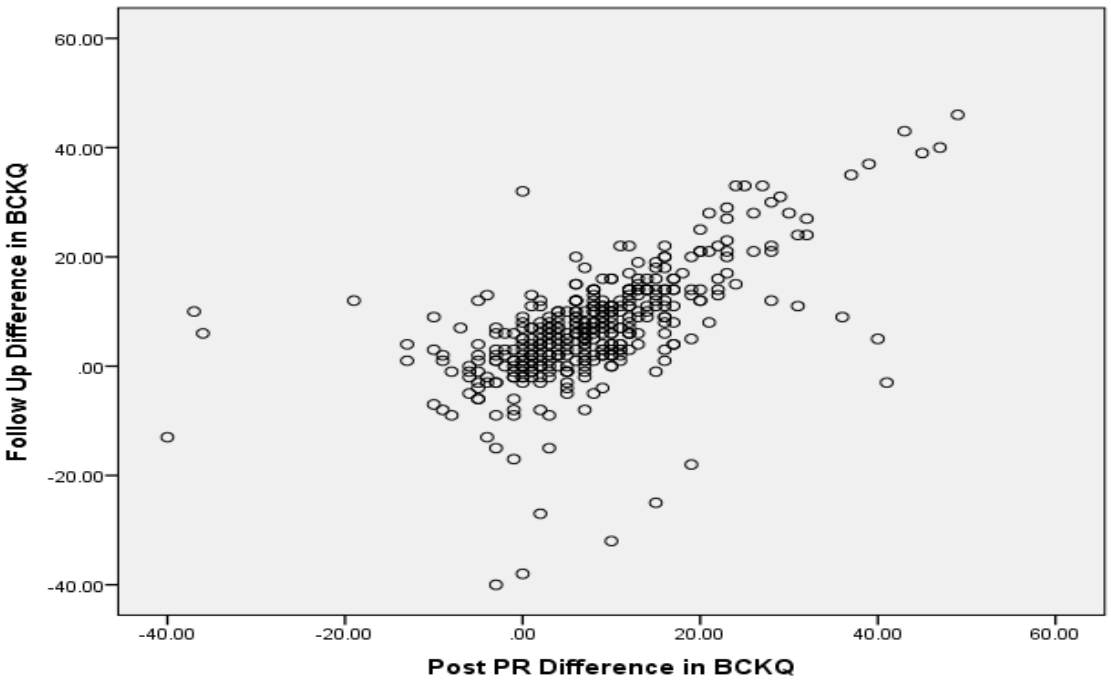

Figure 3.7 – Scatterplot of the relationship between changes in self-management knowledge

There was only a weak negative correlation (see Figure 3.8) between change from baseline in BCKQ score at the follow up stage and changes from baseline in HADS-A at the same stage (Pearsons r=-0.105, p=0.038).

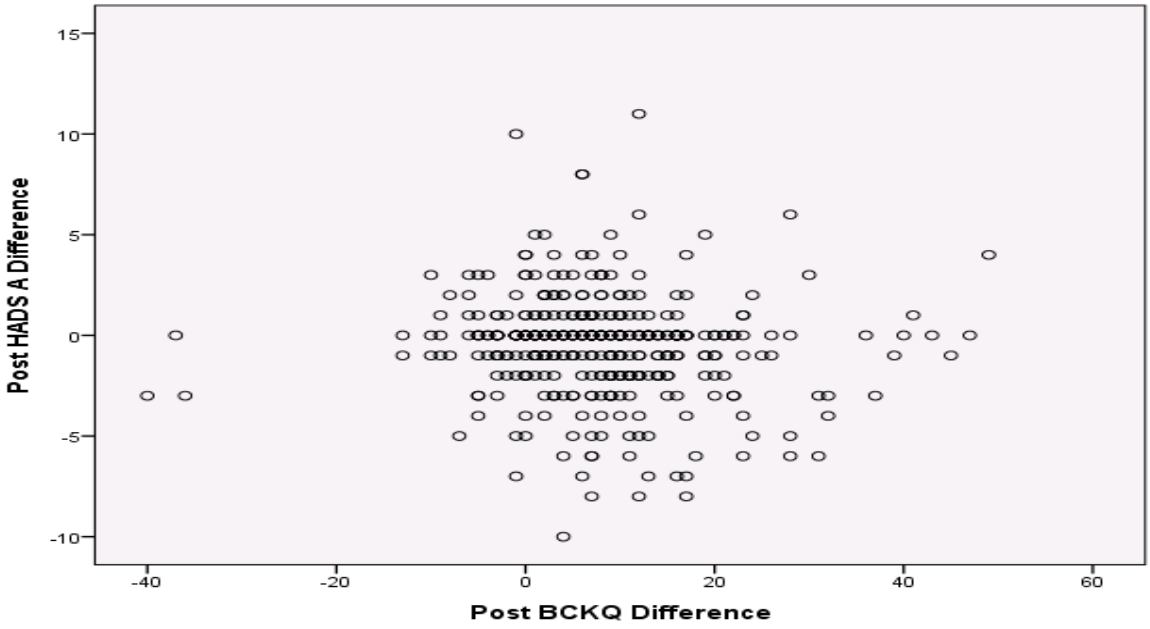

Figure 3.8 - Scatterplot of the relationship between reassessment changes in self-management knowledge and changes in emotional functioning (anxiety)

Similarly, follow up change from baseline in BCKQ score at the follow-up stage (see Figure 3.9) showed only a weak positive correlation with change from baseline in SWT at the same stage (Pearsons r=0.110, p=0.033).

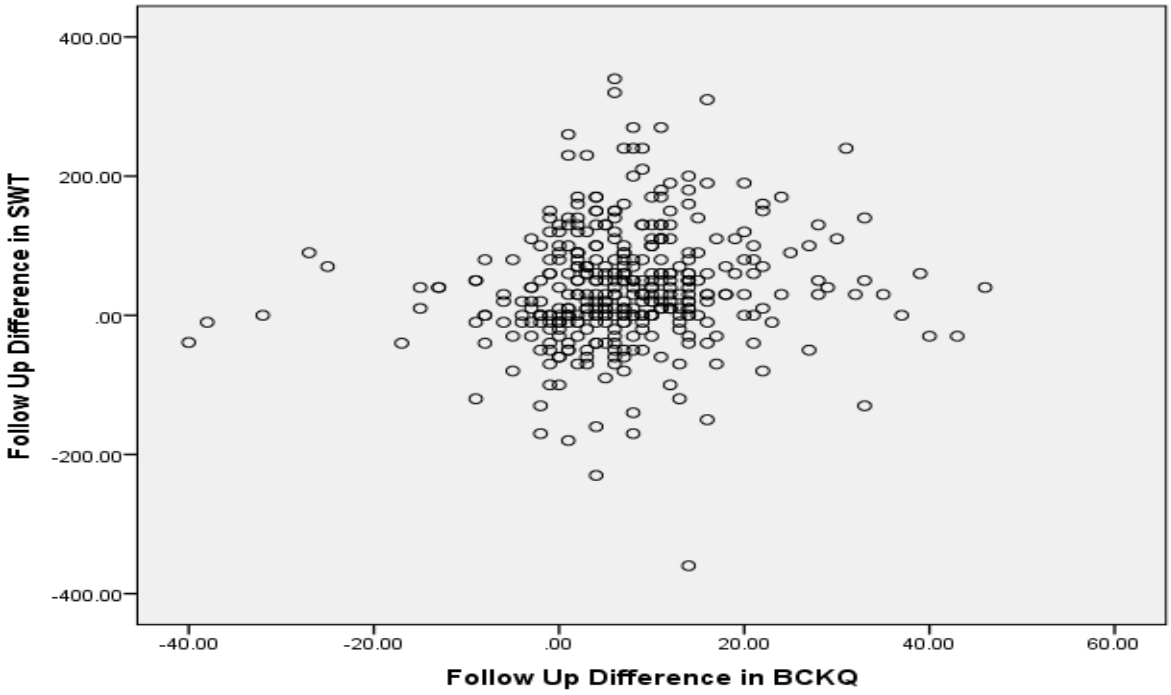

Figure 3.9 - Scatterplot of the relationship between follow up changes in self-management knowledge and changes in functional capacity (SWT)

3.7 DISCUSSION

The main finding of this retrospective analysis of PR data was that statistically significant positive changes were observed in functional capacity, respiratory disability, emotional functioning and self-management knowledge post Liverpool PR intervention which incorporated a COPD self-management education into the rehabilitative process. These changes appear to be maintained three months post-completion of the programme apart from emotional functioning (anxiety) component, which appears to continue to improve. However, there was a lack of a relationship between self-management using the BCKQ and other clinical outcomes, i.e., functional capacity, respiratory disability and emotional functioning. The lack of a relationship may be due to the self-management strategy not being able to effect change in health outcomes or a flaw in the measure of self-management being used.

3.7.1 Characterisation of the Patient Cohort

This patient cohort had a mean age of 66.6 years which is typical for COPD (NICE, 2010) and consistent with the mean age of similar studies such as described by Cosgrove et al., (2013). The study cohort had slightly more female than male COPD patients, were mostly ex-smokers and mainly comprised of patients from the most socio-economically deprived areas of the city. The socio-economic trend is consistent with established evidence that socio-economic factors may play an important role in the development of COPD (Office for National Statistics, 2007 and Department of Health, 2010): According to the ONS (2007), smoking is also more highly represented in lower socio-economic groups and the Department of Health (2010) suggests that the routine and manual occupational group represents almost half of the people with COPD in England, further increasing the risk of developing COPD in this population.

Baseline characteristics of the patients who did or did not attend the pre-intervention assessment seemed to suggest that younger patients with mild COPD who smoked or were more socioeconomically deprived were more likely not to attend than patients with more severe COPD, ex-smokers and less socioeconomically deprived. These findings are consistent with the findings of a systematic review by Keating et al. (2011) into what prevents people with COPD from attending PR. In terms of non-attenders of the Liverpool PR patient cohort, these patients included a small subgroup of younger than usual COPD patients with drug induced COPD; these patients may be more likely to struggle with attending the programme due to health comorbidities secondary to their substance abuse and addiction, which may severely limit their ability to engage or attend PR.

In general, younger patients may also be more likely to be of working age and therefore have work commitments or financial obligations that necessitate working to earn and so are unable to attend. In addition, Fischer et al. (2009), in their research into the role of clinical and psychosocial variables in drop-out and attendance of PR, cited inconvenient timing of the PR programmes as a factor in COPD patients not being able to attend. Another limitation to consider is that younger patients may also have family commitments such as young children, meaning that coordinating attending a series of rehabilitation session on a weekly basis for a period of eight weeks may be a challenge. Patients who are still smoking were identified by Sabit et al. (2008), Steele et al. (2010) and Keating et al. (2011), this may be due to these patients being unprepared to commence the behavioural change advocated by smoking cessation advice, which is a vital part of self-management education for COPD (NICE, 2004 and 2010). In addition, perhaps the

patient burden of attending for a relatively lengthy period of time, even on a weekly basis, may pose a challenge to patients who are in essence on the breadline, facing financial constraints and may need to prioritise their spending, especially if they are on benefits or unable to work to earn a decent wage due to their health. For example, Keating et al. (2011) found that problems with travel and transport such as cost of travel, problems with parking and limited access to public transport were a major barrier to completing PR. In view of only having five community-based and one hospital-based PR clinic sites across the city, it is conceivable that patients within the Liverpool cohort may also experience these challenges.

3.7.2 Clinical Outcomes

The results demonstrated improvement in functional capacity, respiratory disability, emotional functioning and self-management at the post-intervention stage. However, in functional capacity, respiratory disability and self-management knowledge, this improvement was sustained but no further improvements were observed following completion of the programme. Emotional function (HADS Anxiety) continued to improve post PR intervention. Sub-group analysis of the study cohort suggests that patients who did not attend the programme were more likely to have poorer baseline levels of functional capacity, higher levels of respiratory disability, worse levels of anxiety, worse levels of depression and had poorer levels of self-management knowledge. These findings are also consistent with the findings of Keating et al. (2011), Disler et al. (2012) and Khdour et al. (2012) which linked high levels of emotional dysfunction with a higher risk of not attending PR and COPD specific non-adherence to clinical regimen.

3.7.3 Self-Management

Baseline levels of BCKQ of 29.9 (SD 10.5) were consistent with baseline levels reported by Hill et al., 2010 (27.6 SD 8.7) and Ward et al., 2011 (28.3 SD 10.3). The BCKQ demonstrated a 21.1% increase from baseline at the post-intervention stage. Although this improvement was not completely sustained over time, the BCKQ score three months post-intervention still demonstrated a significant change of 19.0% from baseline. Preliminary analysis of the results seemed to show very little or no correlation between changes in self-management knowledge and changes in functional capacity or emotional functioning. This unexpected finding was inconsistent with findings from Bourbeau and Bartlett (2008), which suggested that improved disease knowledge, understanding of treatment benefits can encourage the development of self-management skills, which leads to improvements in function and emotions.

This therefore posed the following questions regarding this lack of correlation:

1. Is the Liverpool PR self-management education strategy able to effect change in health outcomes for patients with COPD?
2. Is the BCKQ an appropriate tool to measure self-management knowledge?

3.7.4 Strengths and Weaknesses of the Study

The strengths of the study included the use of validated outcome measures such as the SWT, MRC dyspnoea scale, HADS, etc., which have good inter-rater and intra-rater reliability. Another strength of the study was the large sample size increasing the precision of estimates, and the fact that it comprised of a range of COPD disease severities, gender, age and respiratory disabilities, thereby increasing the generalisability of the findings to the wider COPD population. The limitations of the study may include its retrospective nature, especially with regard to missing data and data errors on the database. Another potential study weakness may be the subjective nature of some of the patient reported outcome measure, such as, the MRC, HADS and BCKQ, which may be subject to social desirability bias. This is a type of response bias (Keene, 2011), which occurs when the responder may feel compelled to provide a more socially acceptable response to a question. This may be problem theoretically with this cohort, because the PR post-intervention questionnaires were completed in the presence of the clinical staff who delivered the intervention.

3.7.5 Implications for Further Research

Self-management is recognised as a critical element of chronic disease management. However, there is little consensus as to a working definition of self-management specific to COPD and particularly in PR (Disler et al., 2012). It is clear from the findings of this study that self-management and self-management education strategies as part of COPD management are complex and challenging, and, in the experience of the Liverpool PR service, may not have the impact on outcome expected from the literature in practice. The literature around self-management in PR is limited, and further research is warranted. However, as highlighted above, before undertaking further research it is necessary to understand the important, active components of self-management strategies and the best measures of improvements in self-management knowledge. Therefore, before proceeding to any further empirical research, a literature review of self-management interventions and how outcome was measured in these studies is needed. In addition to the above, the findings of this database study generated information that would be useful in future empirical research. For example, in the estimation of an appropriate sample size and accrual rate for a prospective study and clarification of

participant selection in terms of disease severity; this will be discussed further in chapter five.

3.7.6 Implications for Clinical Practice

The improvements in function, respiratory disability and emotions over time provide evidence of the effectiveness of PR programmes in the real world. Self-management knowledge also increased suggesting that self-management had an impact but it declined slightly three months after completion of the PR programme and there may be a need to refresh patients' knowledge over time. However, the findings of the study that there was no relationship between self-management and function, disability and emotions raise questions about the overall effectiveness of self-management strategies, components of these strategies and the appropriate methods of measurement in routine PR practice. This is consistent with the lack of clarity about these issues in the literature; which is further backed up by the findings of the survey reported in Chapter Two. Clinicians need further guidance, but this study cannot provide clear recommendations as it appears to raise more questions and further research is needed. The following chapters explore these issues in more depth and the implications for clinical practice are discussed in the final chapter.

Based on the observed characteristics of the attenders and non-attenders, it appears that the participant's baseline self-management knowledge may influence the completion of the programme and attendance at the follow up assessment. Patients with a poor self-management knowledge of their condition may be more likely to have limited insight into their condition or its management and are therefore less likely to comply with a non-acute management strategy such as pulmonary rehabilitation. Clinicians should be aware of this and may wish to consider mechanisms to promote PR in these groups.

This study has shown the utility to both practice and research of routinely collecting outcome data on patient cohorts. The process of cleaning the data for the research project revealed missing data and input errors; this illustrates the need for constant quality assurance of clinical databases. The Liverpool PR programme used a hetereogeneous method of measuring functional capacity. Patients were asked to complete either a Six Minute Walk Test (6MWT) or Incremental Shuttle Walk Test (ISWT) according to the clinician's assessment of their capability. It is important not to over-reach the capabilities of patients in assessment, but different decisions by different clinicians, as well as, attempts to combine data from different assessments, makes it difficult to assess overall impact of the service on the cohort of patients. This was further

compounded in this study because the different assessment methods were discovered to be indistinguishable on the PR database. Clinicians need to consider the most appropriate measure that can be applied to the vast majority of their patients.

3.8 CONCLUSION

The overall findings of the study showed functional capacity, self-management knowledge and emotional functioning in patients with COPD improved post PR intervention. Early improvements in functional capacity and emotional functioning (depression) were sustained and emotional functioning (anxiety) continued to improve in the short term but improvement in self-management knowledge was not fully sustained in the short term. However, there appeared to be no substantial correlation between self-management and the other clinical outcomes, raising questions about the effectiveness of the Liverpool self-management education strategy and the suitability of the measure of self-management being used, that is, is the BCKQ truly a measure of self-management? In the next chapter, a literature review to explore the evidence on self-management strategies and measures of self-management will be presented.

CHAPTER FOUR

A LITERATURE REVIEW OF COPD SELF-MANAGEMENT, SELF-MANAGEMENT EDUCATION AND SELF-MANAGEMENT EDUCATION EVALUATION USING SYSTEMATIC REVIEW METHODOLOGY

4.1 INTRODUCTION

In the previous chapter, retrospective analysis of health outcomes from patients who had attended Pulmonary Rehabilitation (PR) at the Liverpool Heart and Chest Hospital indicated that self-management knowledge, functional capacity and emotional functioning can improve with PR. However, there was only weak evidence of a relationship between changes in functional capacity or emotional functioning and changes in self-management knowledge. These findings posed questions regarding the suitability of the Bristol COPD Knowledge Questionnaire (BCKQ) as a measure of self-management knowledge and whether other measures may better measure self-management. Alternatively, the appropriateness and effectiveness of the self-management component of the Liverpool PR programme might be called into question. Consequently, a literature review using systematic methods was undertaken to further explore the evidence available on self-management education strategies in order to evaluate whether the Liverpool PR self-management programme was appropriate, what health outcomes it is expected to affect and what tools are appropriate to measure self-management. In this chapter, the methods of the literature review of the evidence are described and the findings reported and discussed.

4.2 RESEARCH STUDENT REFLECTION

At this point in my PhD journey (2012), there was some uncertainty about where my research would take me. The findings of retrospective analysis of routinely collected PR data posed questions about the efficacy of the Liverpool self-management strategy and the measure of self-management being used, i.e., did this self-management education strategy have the ability to effect change in health outcomes for patients with COPD? Was the BCKQ an adequate measure of self-management in this patient group? Before I could progress my project further, I had to look beyond the North West of England to review what the components of self-management education strategies were, how they were measured and how they effected change on health outcomes. I had initially thought that I might need to review self-management education strategies in other long-term conditions such as asthma, chronic heart disease and diabetes due to the sketchy body of evidence available on self-management in COPD. However, I found that the body of evidence on self-management in COPD had developed in the two years since the start

of the thesis and that by 2012, there appeared to be a sufficient evidence base with which to compare the Liverpool self-management education strategy.

4.3 METHODOLOGICAL APPROACH

At this stage of the programme of study, given the results of the previous study, the research student felt that it was imperative that she developed a better understanding of the available research on self-management before proceeding with any further research. This included an insight into what theoretical constructs underpin self-management within studies, how these self-management interventions are delivered, what tools have been used to measure change in self-management and what impact self-management has had on other health outcomes. This fits with the MRC framework; Craig et al. (2008) state that when developing the a complex intervention, identifying what is already known about similar interventions and the methods that have been used to evaluate them is vital and recommend a high quality systematic review of the relevant evidence in the absence of recent research.

A literature review as a comprehensive study and interpretation of literature that addresses a specific study (Aveyard, 2010). There are different types of literature review, including, narrative, critical, scoping, conceptual, state of the art and systematic reviews: Grant and Booth (2009) described the different types of literature review as follows:

- **Narrative review -** provides a narrative or description of what related research has already been conducted
- **Critical review -** comprises of a detailed examination of the literature for comparative purposes and to evaluate a number of perspectives
- **Scoping review –** usually conducting prior to research for the purpose of identifying gaps in the literature, therefore providing a rationale for the research
- **Conceptual review –** identifies the consensus on a topic by reviewing groupings of articles either thematically, or according to concepts or categories. This provides a snapshot of the research subject and attempts to determine whether a greater understanding can be suggested on the topic
- **State of the art review –** this type of review is usually conducted periodically and focuses on the most recent research on a subject, identifying where consensus has been reached and where there are still disagreements
- **Systematic review –** this type of review involves the systematic search of the literature on a particular subject, identifying the best quality studies to form conclusion based on the analysis of the findings from those studies

Based on these definitions, a narrative literature review was dismissed as to gain an understanding of this complex intervention and its impact, a full evaluation of the evidence, not just a description would be required (Craig et al., 2008; Moore et al., 2015). A critical literature review was deemed insufficient to provide the information the research student would require to develop a better understanding of self-management in the context required for this programme of study. Although comparison of different

perspectives on self-management would have been useful, the research student was pursuing a true understanding of the concept of self-management and how it worked in practice, that is, in terms of the tools used to measure self-management, the effect of self-management on health outcomes and the relationship between self-management and other health outcomes. In this instance, a scoping literature review had already been carried out at the start of the programme of study and as the programme was underway, a more detailed specific search with specific questions to answer was required to inform this stage of the research. The research student disregarded the pursuit of a conceptual literature review due to the relatively small body of evidence on self-management at the time and the lack of consensus from previous Cochrane reviews on self-management within this patient group to be able to analyse articles according to concepts, categories or themes (Grant and Booth, 2009). A state of the art literature review was also disregarded as periodic reviews of the available research was not required for the purpose of this literature review; the research student needed to draw on existing evidence and theory at one specific time point to inform the design for the progression of the research. A review of the literature using systematic methods to examine the available research on self-management education was deemed the most appropriate strategy to develop a theoretical understanding of self-management education and the likely process of change with the application of self-management education as an intervention incorporated into PR. The systematic methodology also provided the research student with an organised framework such as the framework demonstrated in the Cochrane Handbook, Version 5.1, (Higgins, Altman and Stern, 2011) to inform the methods used: Although two reviewers are preferable, due to resource constraints, a single reviewer (the research student) carried out the literature review. In this case, the use of a pre-specified systematic methodology, such as that outlined in the Cochrane Handbook, reduced the risk of deviation from the set parameters for the literature review, therefore minimising the scope for bias.

4.4 AIM OF THE LITERATURE REVIEW

The main aim of this literature review, using systematic methods, was to review the current evidence available on self-management education and to ascertain what outcome measures should be used to evaluate self-management. A previous broad search of the literature (reported in Chapter One) had suggested that there may be a limited body of evidence on self-management education relating to COPD as not many papers on multi-component self-management in COPD had been found. This was supported by the findings of a Cochrane review, which concluded that the role of self-management education as part of PR for COPD patients is poorly researched and there is insufficient evidence regarding the effectiveness of this aspect of COPD management on functional capacity and emotional functioning (Effing et al., 2009). The latest Cochrane review of PR by McCarthy et al. (2015) suggests that there are elements of PR, including self-management that require further consideration and research. Therefore, the initial scope of the literature review was extended to include other chronic conditions such as

diabetes, heart failure and asthma. Diabetes was chosen because there have been established self-management programmes. Heart failure and asthma were chosen because of the similarity in disease prognosis, disease effect, symptoms and treatment strategies, including medication with COPD.

4.5 OBJECTIVES OF THE LITERATURE REVIEW

The objectives of this literature review using systematic methods were as follows:

1. To identify different types of strategies used to deliver self-management education.
2. To review the evidence on the impact of self-management education strategies on health outcomes.
3. To ascertain what measures are used to assess self- management education.

4.6 METHOD

4.6.1 Selection Criteria

The inclusion criteria for selection of studies included:

1. studies or articles pertaining to adults
2. studies undertaken in primary, secondary or tertiary healthcare settings
3. studies with a structured self-management education programme intervention, which was delivered by a qualified healthcare professional using group based, direct contact (telephone or web-based in conjunction with other strategies) or face-to-face formats
4. studies which were RCTs - by limiting included studies to RCTs, the research student was trying to ensure that the evidence reviewed could be categorised as being of the highest quality using the Grades of Recommendation, Assessment, Development and Evaluation (GRADE) approach (Dijkers, 2013)
5. studies that included one or more of the following outcome measures:
    a) functional capacity
    b) emotional functioning
    c) health related quality-of-life
    d) exacerbations
    e) admissions to hospital
    f) medication use
    g) compliance
    h) health behaviour
    i) self-efficacy or confidence
    j) symptom monitoring skills and management skills.

4.6.2 Search Strategy

A review of literature from the following bibliographic databases using systematic methods was conducted by a single reviewer:

- AMED
- CINHAL
- EMBASE
- PubMed
- PsychInfo

The following keywords were used as part of the search strategy:

1. (Self-management *OR* Self care) *AND* Education *AND* COPD

The Medical Subject Heading (MeSH) terms were: self-management education as the topic, using the following variants, self-care or self care, self-management or self management and the pathology, i.e., asthma, diabetes, COPD, heart failure.

The search was limited to articles in English because of lack of access to and resources for translation and a time limit for the publication year (2000 – 2012) was applied. The rationale for the time limit application was that the management of the chosen conditions prior to these dates would not be comparable to current practice as evidenced by the following guidelines for each chronic disease:

1. Asthma - BTS/SIGN (2001, 2003, annually 2004 - 2012), ATS (2009, 2010)
2. COPD - BTS (2001), CSP (2003), ATS (2004), NICE (2004, 2010)
3. Diabetes – SIGN (2001, 2010), NICE (2009)
4. Heart failure – SIGN (2007), ACC/AHA (2005), NICE (2010), ECS (2012)

These guidelines chart the evolution of clinical management of these long-term conditions over time. In order to evaluate the generalisability of the Liverpool PR self-management strategy compared to the available body of evidence, it was vital to be able to compare the Liverpool PR self-management education strategy with up-to-date or current evidence-based practice.

This search strategy produced a list of abstracts from which an initial screening for potentially suitable studies based on the title of the selected articles was carried out. The abstracts of these articles were then reviewed for their suitability to be included in the study. The full article of studies which met the inclusion criteria were obtained and compared against the inclusion and exclusion criteria. Studies that met the inclusion criteria were selected for detailed review.

4.6.3 Data Extraction

The data extraction was also carried out by the same single reviewer (the research student). Data was extracted using a simple data extraction form created for the study (see Table 4.1). Information on the study type, setting, condition, number of participants, population characteristics and study details, including the self-management intervention strategy, the tools used to measure health outcomes and the intervention effect observed (see Appendix 26 for full study data extraction form).

Table 4.1 – Literature Review Data Extraction Form

Study Design			Study Population				Study Outcome	
Authors	Year of Publication	Type of Study	Condition	Country and Setting	Number of Participants	Population characteristics	Study details and self-management delivery method(s)	Study results

4.6.4 Assessment of Risk of Bias in Included Studies

Only a brief quality assessment was carried out using a risk of bias tool for descriptive purposes of the body of evidence. The rationale for this was that the purpose of the review was to explore the self-management methods and the measures used to evaluate self-management in order to inform the design of the prospective study rather than to determine the intervention effect of self-management education.

The risk of bias for each study included in the literature review was assessed according to recommendations outlined in the Cochrane Handbook for Systematic Reviews of Interventions, Cochrane Handbook, Version 5.1, (Higgins, Altman and Stern, 2011) for the following items:

1. random sequence generation
2. allocation concealment
3. blinding of participants and personnel
4. blinding of outcome assessment
5. incomplete outcome data
6. selective outcome reporting
7. other bias

The single reviewer (the research student) assessed for all items outlined above and categorised the risk of bias being present as being high, low or unclear. Unclear risk indicated that insufficient detail of what happened in the study was reported, that what happened in the study was known but the risk of bias was unknown or that an entry was not relevant to the study.

4.6.5 Analysis

Given the purpose of the review, a descriptive narrative of the self-management education strategies used, the intervention effects observed and what outcome measures were used to assess the intervention effect(s) was carried out by the same single reviewer.

4.7 RESULTS

The search was carried out on the 16/12/2012. The search identified 386 citations across the four chronic diseases with 126 papers being selected for review of the abstract. The number selected for detailed review was 66 (asthma n=18, COPD n=16, diabetes n=22 and heart failure n=10). Forty-nine of these 66 papers met the inclusion criteria for the literature review (asthma n=16, COPD n=13, diabetes n=11 and heart failure n=7).

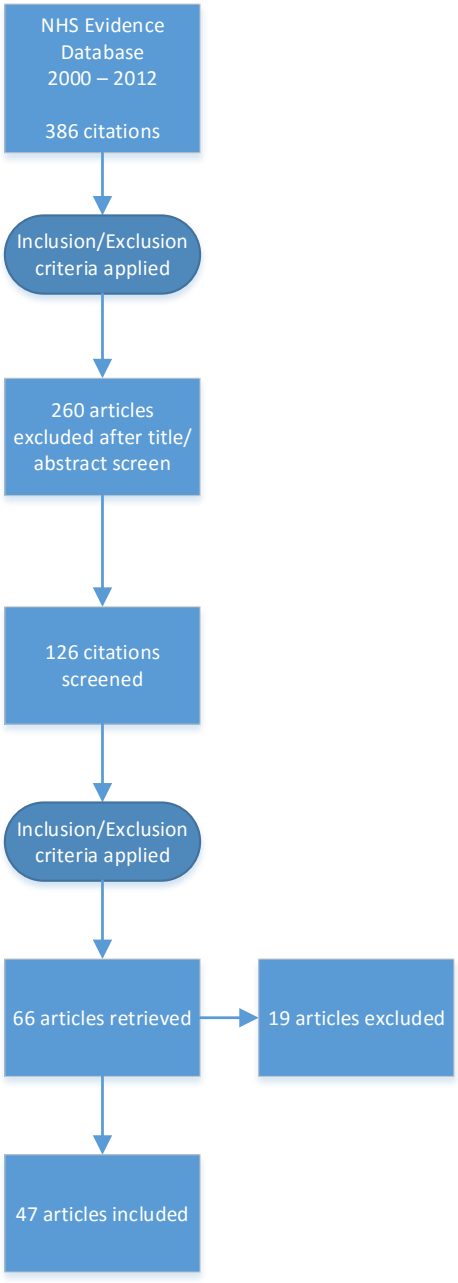

Figure 4.1 – Self-Management PRISMA Flowchart

Table 4.2 – Article Selection

Search Number and Term	Asthma	COPD	Diabetes	Heart failure	Total
Total papers selected from database	19	43	63	261	386
Paper selected from reference lists for review of abstract	19	29	44	34	126
Total number of citations undergoing detailed review	18	16	22	10	66
Papers meeting inclusion criteria and included in final review	16	13	11	7	47

As the number of COPD studies identified was higher than anticipated and the self-management strategies utilised across the four different long-term conditions were similar with similar observed intervention effects, the decision was made to focus the analysis from this point onwards on the findings from the COPD self-management studies.

COPD Articles

Sixteen COPD related citations were reviewed in detail and out of those three COPD studies were excluded (see Table 4.3). The number of COPD papers that met the inclusion criteria for the literature review was thirteen.

Table 4.3 - Characteristics of Excluded Studies (n=3)

Excluded Study	Reason for Exclusion
Faulkner, 2010	Non-health professional delivered COPD intervention
Nguyen et al., 2009	Single health professional using single component COPD self-management education strategy (mobile phone-based individual teaching and advice)
Nguyen et al., 2008	Single health professional using single component COPD self-management education strategy (internet-based individual teaching and advice) in a primary care setting and secondary care clinic

Table 4.4 - Summary of Findings (n=13)

Reference	Summary of Findings
Gallefoss and Bakke (2000)	Patient self-management education can reduce the need for GP visits and kept a greater proportion of patients independent of their GP during a 12-month follow-up. Increasing number of GP visits was associated with decreased HRQoL in both groups.
Bourbeau et al. (2003)	A self-management programme for COPD improves appropriate medication use and intervention points in COPD and can reduce admissions to hospital.
Monninkhof et al. (2003)	A non-concurrent self-management education and physical training programme had no effect on HRQoL, walking distance, breathlessness, sputum production, cough or patient self-confidence.
Hesselink et al. (2004)	A semi-structured self-management programme can improve inhalation techniques although it did not effect any change in symptoms or HRQoL.
Bourbeau et al. (2006)	A self-management programme for COPD can significantly lower the frequency of hospital admissions, shorten length of hospital stay per patient, reduce emergency department visits and unscheduled physician visits and is more cost effective than usual clinical care.
McGeoch et al. (2006)	A structured self-management plan can improve disease knowledge in patients with COPD.
Efraimsson et al. (2008)	A multi-component self-management programme can significantly reduce COPD patient symptoms, increase in activities, reduce the impact of COPD on psychosocial health, improve HRQoL, improve health-related behaviours and COPD knowledge.
Khdour et al. (2009)	A multi-component self-management education strategy can reduce unscheduled healthcare utilisation and hospital admissions. Significant improvement in patient adherence, symptoms and disease impact can also be achieved through the use of a multi-component self-management education strategy.
Sedano et al. (2009)	The self-management programme led to changes in patient behaviour, i.e., more than 50% of patients promptly self-treated their exacerbations with antibiotics and Prednisolone. This appropriate adoption of self-management was associated with a reduction in hospital admissions and emergency visits.
Trappenburg et al. (2011)	The study found no difference in HRQoL or emotional functioning (anxiety and depression) with the self-management education strategy, the results did indicate that exacerbations have a high impact on health status with longer recovery time being associated with poor health status.
Wakabayashi et al. (2011)	An integrated COPD self-management education strategy improved patient information needs, ADL, dyspnoea and BODE index as well as reduced the number of hospital admissions.
Fan et al. (2012)	The study was unable to show a theory based Comprehensive Care Management Programme reduced COPD related hospitalisations.
Siddique et al. (2012)	A practical educational intervention incorporating principles of chronic disease management may reduce the rate of breathing related hospitalisations in some patients with COPD.

4.7.1 Participants and Recruitment

Thirteen studies on 6616 participants compared COPD self-management to usual COPD management. The number of participants ranged from n=52 to n=4425 with six studies recruiting study participants from primary care, six studies recruiting from secondary care and one study recruiting participants from dual healthcare settings (primary and secondary care). Six studies (46.2%) were European based studies, from the Netherlands (n=3), Norway (n=1), Sweden (n=1) and the UK (n=1). Five studies (38.5%) were North American based: Canada (n=3) and the USA (n=2). The other studies were based in Japan (n=1) and New Zealand (n=1) respectively – see Table 4.4 for summary table of included studies and Appendix 20 for a more detailed table on the studies.

4.7.2 Interventions

COPD self-management intervention used a variety of and a combination of a variety of methods (face-to-face assessment and treatment, telephone based monitoring or supervision, 1:1 sessions, group sessions, theoretical education or practical skill based sessions in conjunction with the use of a variety of self-management educational materials). Studies compared self-management education intervention to usual care, with usual care being an out-patient based clinical intervention by a healthcare professional such as a nurse, GP or physician in a health-based individual face-to-face consultation in primary or secondary care. It is important to note that none of the interventions were considered as PR or embedded in a PR service.

Three studies (Fan et al., 2012; Bourbeau et al., 2006; Bourbeau et al., 2003) compared usual care with a self-management programme consisting of self-management education programme, home exercise programme, action plan for exacerbation and telephone follow-up. Three studies (Wakabayashi et al., 2011; Gallefoss and Bakke, 2000; Sedano et al., 2009) compared usual care to individualised COPD self-management programmes (self-management package and action plan, individualised COPD self-management programme based on the Lung Information Needs Questionnaire and a comprehensive management brochure). Three studies (Fan et al., 2012; Khdour et al., 2009; Efraimsson et al., 2008) compared usual care with enhanced usual care in conjunction with a COPD self-management education and self-management plan. One study (Siddique et al., 2012) compared usual care to a self-management programme consisting of a patient brochure, self-management group sessions and 1:1 COPD self-management education. Another study (Hesselink et al., 2004) compared usual COPD care in primary care with a self-management programme consisting of 1 – 4 health consultations and a 1:1 COPD self-management education

programme. One study (Monninkhof et al., 2003) compared usual care to a COPD self-management programme consisting of a COPD action plan, education booklet, physical training programme and a self-management education course. One study (Trappenburg et al., 2011) compared usual care to a self-management programme consisting of an education package and COPD action plan in conjunction with support and supervision from a case manager. Follow-up intervals in the studies were, three to five months in one study (Efraimsson et al., 2008), six months in one study (Trappenburg et al., 2011), 12 months in eight studies (Siddique et al., 2012; Wakabayashi et al., 2011; Khdour et al., 2009; Sedano et al., 2009; Bourbeau et al., 2006; McGeoch et al., 2006; Bourbeau et al., 2003; Gallefoss and Bakke, 2000) and 24 months in two studies (Hesselink et al., 2004; Monninkhof et al., 2003). One study (Fan et al., 2012) was terminated early due to excessive mortality in the intervention group, the intended follow-up period for this study was 12 months.

4.7.3 Outcome Measures and Self-Management Education Intervention Effect

A variety of health outcomes were utilised in the thirteen studies to evaluate the intervention effect of the self-management education programme. The health outcomes used in these 13 studies can be categorised into eight themed categories as follows:

1. adherence and self-care behaviour
2. COPD signs and symptom management
3. disease knowledge
4. emotional functioning
5. functional capacity
6. healthcare utilisation and cost
7. health related quality-of-life and health status
8. self-efficacy

The findings of the literature review have been summarised in the table overleaf (see Table 4.5 and Appendix 20 for detailed study findings).

Table 4.5 – Summary Table of Outcomes and Self-Management Education Intervention Effect

Outcomes	Summary of Findings/Intervention Effect
Adherence and Self-care Behaviour	
Medication use (n=4) (Bourbeau et al., 2003; Hesselink et al., 2004; Sedano et al., 2009; Fan et al., 2012)	One study (7.7%) by Bourbeau et al. (2003) showed similar medication use in both control and intervention groups but showed less oral steroid use in the intervention group compared with the control group. One study (7.7%) by Hesselink et al. (2004) showed improved used of inhaled therapy in the intervention group compared to the control group. One study (7.7%) by Sedano et al. (2009) demonstrated increased antibiotics use in the intervention group compared to the control group. Another study (7.7%) by Fan et al. (2012) showed increased oral steroid use in the intervention group compared to the control group.
Patient adherence (n=2) (Khdour et al., 2009; Sedano et al., 2009)	One study (7.7%) by Khdour et al. (2009) demonstrated significant improvement in patient adherence in the intervention group compared to the control group and another study (7.7%) by Sedano et al. (2009) demonstrated positive change in behaviour in more than 50% of the self-management education group.
Smoking/smoking cessation (n=3) (Efraimsson et al., 2008; Khdour et al., 2009; Wakabayashi et al., 2011)	One study (7.7%) by Efraimsson et al. (2008) demonstrated increased smoking cessation in the intervention group compared to the control group. One study (7.7%) by Khdour et al. (2009) showed no difference in smoking between the control and intervention groups. Another study (7.7%) by Wakabayashi et al. (2011) showed smoking worsened in the control group compared with the intervention group.

Outcomes	Summary of Findings/Intervention Effect
COPD Signs and Symptom Management	
Body Mass Index (n=1) (Khdour et al., 2009)	One study (7.7%) by Khdour et al. (2009) showed no difference in BMI between the control and intervention groups.
COPD symptoms e.g., dyspnoea (n=6) (Monninkhof et al., 2003; Hesselink et al., 2003; Efraimsson et al., 2008; Khdour et al., 2009; Trappenburg et al., 2011; Wakabayashi et al., 2011)	Five studies (38.5%) by Hesselink et al. (2004), Efraimsson et al. (2008), Khdour et al. (2009), Trappenburg et al. (2011) and Wakabayashi et al. (2011) demonstrated significant improvements in COPD symptoms in the intervention group compared to the control group. One study (7.7%) by Hesselink et al. (2004) showed no difference in dyspnoea between control and intervention groups but another study (7.7%) by Wakabayashi et al. (2011) demonstrated significant improvement in dyspnoea in the intervention group compared to the control group. Another study (7.7%) by Monninkhof et al. (2003) showed no difference in COPD symptoms such as coughing and sputum between control and intervention groups.
Mortality (n=1) (Fan et al., 2012)	One study (7.7%) by Fan et al. (2012) showed significantly higher mortality in the intervention group compared to the control group.
Number of exacerbations (n=1) (Trappenburg et al., 2011)	Only one study (7.7%) by Trappenburg et al. (2011) showed a reduction in the number of exacerbations in the intervention group compared to the control group.
Spirometry (n=2) (Bourbeau et al., 2003; Khdour et al., 2009)	Two studies (15.4%) by Bourbeau et al. (2003) and Khdour et al. (2009) demonstrated no difference in lung function or spirometry between the control and intervention groups.
BODE Index (n=1) (Wakabayashi et al., 2011)	One study (7.7%) by Wakabayashi et al. (2011) reported significantly improved BODE index scores in the intervention group compared to the control group which demonstrated worsened BODE index scores at 12 months.

Outcomes	Summary of Findings/Intervention Effect
Disease Knowledge	
COPD knowledge Questionnaire (n=2) (Khdour et al., 2009; Fan et al., 2012)	One study (7.7%) by Fan et al. (2012) showed no difference in COPD knowledge between the control and intervention groups. Another study (7.7%) by Khdour et al. (2011), reported higher knowledge scores in the intervention group at six and 12 months compared to the control group.
COPD Knowledge rating (n=1) (Efraimsson et al., 2008)	One study (7.7%) by Efraimsson et al. (2008) reported significant difference in knowledge about COPD between the intervention and control groups.
Lung Information Needs Questionnaire (n=4) (McGeoch et al., 2006; Effraimsson et al., 2008; Khdour et al., 2009; Wakabayashi et al. 2011)	Four studies (30.8%) by McGeoch et al. (2006), Efraimsson et al. (2008), Khdour et al. (2009) and Wakabayashi et al. (2011) demonstrated significant improvement in COPD knowledge and lung information needs in the intervention group compared to control.
Emotional Functioning	
Disease impact on psychosocial health (n=3) (McGeoch et al., 2006; Efraimsson et al., 2008; Trappenburg et al., 2011)	Two studies (15.4%) by McGeoch et al. (2006) and Trappenburg et al. (2011) showed no difference in psychological and emotional functioning when comparing usual COPD care with self-management intervention. Another study (7.7%) by Efraimsson et al. (2008) demonstrated a significant improvement in the impact of disease on psychosocial health in the intervention group compared to the control group.
HADS (n=2) (McGeoch et al. 2006; Trappenburg et al., 2011)	Two studies by McGeoch et al. (2006) and Trappenburg et al. (2011), reported no difference in emotional functioning between the intervention and control groups or change in anxiety and depression.

Outcomes	Summary of Findings/Intervention Effect
Functional Capacity	
Six Minute Walk Test (n=2) (Bourbeau et al., 2003; Monninkhof et al., 2003)	Two studies (15.4%) by Bourbeau et al. (2003) and Monninkhof et al. (2003) showed no difference between control and intervention groups.
Physical activity (n=2) (Efraimsson et al., 2008; Wakabayashi et al., 2011)	Two studies (15.4%) by Efraimsson et al. (2008) and Wakabayashi et al. (2011) showed significant improvement in walking distance or physical activity in the intervention group compared to the control group.
Healthcare Utilisation and Cost	
Absenteeism from work (n=1) (Gallefoss and Bakke, 2000)	One study (7.7%) by Gallefoss and Bakke (2000) showed reduced absenteeism from work in the intervention group compared to the control group.
Cost and Healthcare utilisation (n=2) (Bourbeau et al., 2003; Bourbeau et al., 2006)	Two studies (15.4%) by Bourbeau et al. (2003 and 2006) showed a reduction in healthcare utilisation, decreased hospital length of stay and reduced healthcare related cost in the intervention group compared to the control group.
Frequency of admissions (n=3) (Wakabayashi et al. 2011; Fan et al., 2012; Siddique et al., 2012)	One study (7.7%) by Fan et al. (2012) was unable to demonstrate a difference in hospital admissions in the intervention and control groups. Five studies (38.5%) by Bourbeau et al. (2003), Khdour et al. (2009), Sedano et al. (2009), Wakabayashi et al. (2011) and Siddique et al. (2012) showed reduction in hospital admissions in the intervention group compared to the control group.
GP visits (n=2) (Gallefoss and Bakke, 2000; Khdour et al., 2009)	Two studies (15.4%) by Gallefoss and Bakke (2000) and Khdour et al. (2009) showed a decrease in GP visits in the intervention group compared to the control group.

Outcomes	Summary of Findings/Intervention Effect
Health Related Quality-of-Life and Health Status	
St Georges Respiratory Questionnaire (n=6) (Monninkhof et al., 2003; Hesselink et al., 2004; McGeoch et al. 2006; Efraimsson et al. 2008; Khdour et al., 2009; Trappenburg et al., 2011)	Four studies (30.8%) by Monninkhof et al. (2003), Hesselink et al. (2004), McGeoch et al. (2006) and Trappenburg et al. (2011) showed no difference in HRQoL between control and intervention groups. Two studies (15.4%) by Efraimsson et al. (2008) and Khdour et al. (2009) showed significant improvement in HRQoL in the intervention group compared to the control group.
Clinical COPD Questionnaire (n=1) (Trappenburg et al., 2011)	One study (7.7%) by Trappenburg et al. (2011) demonstrated significantly lower symptom and functional scores in the intervention group compared to the control group.
HRQoL (n=3) (Gallefoss and Bakke, 2000; Hesselink et al., 2004; Khdour et al., 2009)	Two studies reported improvements in health status - Gallefoss and Bakke (2000) found increasing number of GP visits was associated with decreased HRQoL in both the control and intervention groups and reported that three times as many GP visits in the COPD control group compared to the intervention group: They also found self-management education can reduce the need for GP visits and kept a greater proportion of patients independent of their GP during a 12-month follow-up: Khdour et al. (2009) reported significant improvement in health status in the intervention group at six and 12 months compared to the control group. One study (Hesselink et al., 2004) reported that HRQoL did not change much during the two year follow-up and no significant differences were found between the intervention and control groups after one and two years.

Outcomes	Summary of Findings/Intervention Effect
Self-Management Measures and Self-efficacy COPD Self-Management Interview (n=1) (McGeoch et al. 2006)	McGeoch et al. (2006) reported statistically significant difference at 12 months in self-management interview scores with higher scores being observed in the intervention group.
Study self-efficacy/confidence questionnaire (n=2) (Monninkhof et al., 2003; Fan et al., 2012)	One study by Monninkhof et al. (2003) showed no difference in self-efficacy and patient confidence. Another study by Fan et al. (2012) demonstrated moderate difference in the rate of steroid use per exacerbation between intervention and control groups.

4.7.4 Overview of Risk of Bias

Overall, the studies reviewed were of good quality (see Table 4.6): All 13 studies demonstrated low risk of selection and concealment bias by having a clear random sequence generation protocol. Blinding of participants and participants was clearly outlined in one study (Trappenburg et al., 2011) but 12 studies did not sufficiently or clearly describe this process, therefore the risk of performance bias was classified as being unclear. Blinding of outcome assessment was specified in seven out of the 13 studies (Bourbeau et al., 2003; Monninkhof et al., 2003; Hesselink et al., 2004; Bourbeau et al., 2006; McGeoch et al., 2006; Trappenburg et al., 2011; Wakabayashi et al., 2011 and Fan et al., 2012). Three studies (Gallefoss and Bakke, 2000; Trappenburg et al., 2011 and Siddique et al., 2012) did not provide sufficient information on attrition or incomplete data to establish a clear level of attrition bias. All thirteen studies reported on the primary and/or secondary health outcomes outlined in the respective study protocols.

An overview of the risk of bias judgements is presented in Table 4.6 below.

Table 4.6 – Risk of Bias

	Random sequence generation (Selection bias)	Allocation concealment (Concealment bias)	Blinding of participants and personnel (Performance bias)	Blinding of outcome assessment (Detection bias)	Incomplete outcome data (Attrition bias)	Selective reporting (Reporting bias)	Other bias
Gallefoss and Bakke, 2000	Low risk	Low risk	Unclear risk	Unclear risk	Unclear risk	Unclear risk	Low risk
Bourbeau et al., 2003	Low risk	Low risk	Unclear risk	Low risk	Low risk	Unclear risk	Low risk
Monninkhof et al., 2003	Low risk	Low risk	Unclear risk	Low risk	Low risk	Unclear risk	Low risk
Hesselink et al., 2004	Low risk	Low risk	Unclear risk	Low risk	Low risk	Unclear risk	Low risk
Bourbeau et al., 2006	Low risk	Low risk	Unclear risk	Low risk	Low risk	Unclear risk	Low risk
McGeoch et al., 2003	Low risk	Low risk	Unclear risk	Low risk	Low risk	Unclear risk	Low risk
Efraimsson et al., 2008	Low risk	Low risk	Unclear risk	Unclear risk	Low risk	Unclear risk	Low risk
Khdour et al., 2009	Low risk	Low risk	Unclear risk	Unclear risk	Low risk	Unclear risk	Low risk
Sedano et al., 2009	Low risk	Low risk	Unclear risk	Unclear risk	Low risk	Unclear risk	Low risk
Trappenburg et al., 2011	Low risk	Low risk	Low risk	Low risk	Unclear risk	Unclear risk	Low risk
Wakabayashi et al., 2011	Low risk	Low risk	Unclear risk	Low risk	Low risk	Unclear risk	Low risk
Fan et al., 2012	Low risk	Low risk	Unclear risk	Low risk	Low risk	Unclear risk	Low risk
Siddue et al., 2012	Low risk	Low risk	Unclear risk	Unclear risk	Unclear risk	Unclear risk	Low risk

4.8 DISCUSSION

A preliminary literature search conducted at the start of this programme of studies provided a definition and description for the concept of patient education, specifically self-management education. It found that patient education is viewed as a vital part of improving the management of any chronic disease and, specifically within the management of COPD, patient self-management is an essential component. According to the British Thoracic Society statement on pulmonary rehabilitation in 2001, patient education is a central feature of pulmonary rehabilitation but is not effective alone in improving health status or physical performance without the other components (British Thoracic Society, 2001). Although improving knowledge is a key component of self-management, it should be used in conjunction with other approaches to facilitate the behavioural change that is required to optimise the management of the patient's condition.

Educational interventions for chronic illnesses aim to provide patients with the knowledge and skills to deal with limitations imposed by the disease. Self-management is a term applied to any formalised patient education programme aimed at teaching skills needed to carry out medical regimens specific to the disease, guide health behaviour change and provide emotional support for patients to control their disease and live functional lives (Bourbeau, 2003). Self-management education programmes are distinct from simple patient education or skills training, in that they are designed to allow people with chronic conditions to take active part in the management of their own condition (Foster et al., 2009). The main aim of this literature review was to review the current evidence available on self-management education and to ascertain what outcome measures should be used to evaluate self-management. Overall, this literature review has achieved this aim by providing an evidence base against which the findings of this programme of study were compared and provided a source of data to inform the design of a prospective study. Bearing these theoretical concepts on self-management education in mind, the findings of this literature review on self-management in COPD were divided into two main categories for further discussion:

1. self-management education strategies
2. self-management education evaluation of outcomes.

4.8.1 Self-Management Education Strategies

Structured Multi-Component Self-Management Education

The format of the self-management education programme is vital in delivering the objectives of the programme itself. All the studies reviewed had structured multi-component self-management education programmes that incorporated information on the following:

1. Nature of the disease
2. Symptoms
3. Symptom monitoring
4. Appropriate medication use including inhaler technique or antibiotics and steroid use
5. Action planning and self-management plans

The multi-component programmes have been linked with:

1. reduced reliance on healthcare professionals and improved HRQoL (Gallefoss and Bakke, 2000)
2. reduction in admissions to hospital and length of hospital stay (Bourbeau et al., 2003)
3. improved medication efficacy (Hesselink et al., 2004)
4. lower healthcare costs (Bourbeau et al., 2006)
5. increased disease knowledge (McGeoch et al. 2006)
6. reduction in patient symptoms, increase in activities that reduced dyspnoea, reduced impact of COPD, improved HRQoL, smoking cessation and improved knowledge of COPD (Efraimsson, 2008)
7. improved symptom and exacerbation management (Sedano et al. 2009)
8. improved understanding of COPD, avoidance of exacerbations, improved dyspnoea, improved disease profile and improved activities of daily living (Wakabayashi, 2011)
9. improved symptom related functional scores and faster response to exacerbations (Trappenburg et al., 2011).

It is important to note that not all multi-component self-management educational strategies showed benefits; the findings from a non-concurrent self-management programme (Monninkhof et al., 2003) indicates that the timing of the interventions may also be an important factor in establishing the efficacy of the intervention: No significant differences were detected in quality-of-life, functional capacity, COPD symptoms or self-efficacy. Confounding factors such as in the study by Fan et al. (2012) resulted in a high mortality rate in the intervention group and the study being terminated.

In general, however, these findings support the self-management theory by Wortz et al. (2012) regarding the multi-factorial nature of self-management; each component in isolation does not necessarily result in effective self-management but, the interaction of improved knowledge, improved symptom control and self-efficacy impact positively on patient quality-of-life. The Liverpool PR self-management education strategy is a multi-component self-management programme that incorporates disease education, medication management and efficacy, symptom monitoring and management, emotional functioning, environmental health, support strategies and mechanisms for coping with COPD that include an individualised action plan for managing exacerbations. As these components are similar to those in the studies from the literature review, it could be assumed that the same effects observed in these studies, could be replicated in the effect of the Liverpool PR self-management strategy on health outcomes for patients with COPD.

Proactive Coping Strategies

In COPD, severity of symptoms can change depending on factors such as the weather, pollutants or during an exacerbation, meaning that even patients who previously felt in control of their condition with regard to symptom management, may feel unable to manage their altered symptoms: The loss of control of the symptoms in chronic disease has been highlighted as a major factor in limiting the patient's ability to self-manage effectively (IOM 2003, NICE 2004, NICE 2010 and Wortz et al., 2012). In this review, Bourbeau et al. (2006) demonstrated that a multicomponent self-management education programme with ongoing supervision by a case manager to assist with action planning can reduce the use of health services and healthcare related costs among previously hospitalised patients with moderate to severe COPD. It could be argued that this reduction is primarily the result of fewer hospitalisations, emergency department visits and unscheduled physician visits. McGeoch et al. (2006) demonstrated that, in patients with COPD in a primary-care setting, the use of a written self-management plan and associated short education package is associated with greater self-management knowledge.

Self-efficacy in turn has been associated with improved symptom control, compliance with medical therapy, improved emotional functioning and improved quality-of-life. This is supported by Siddique et al. (2012) who suggest that a practical educational intervention incorporating principles of chronic disease management may reduce the rate of breathing related hospitalisations in the large proportion of patients with COPD who are at relatively low-risk for such events. Their findings indicated that self-management education with a focus on effective management and proactive coping

strategies can improve self-management knowledge, coping skills, goal attainment, self-efficacy and healthcare utilisation in patients with long-term conditions. In this case, however, it would appear that the researcher's ability to validate their findings were severely limited by the study cohort, who were identified as being low risk of breathing related hospitalisations, most likely due to the mild nature of their disease.

The Liverpool PR self-management education strategy incorporates elements of medication management and efficacy, symptom monitoring and management and mechanisms for coping with COPD which includes an individualised action plan for managing exacerbations. Particular emphasis is placed on action planning, exacerbation management and environmental health issues during high-risk periods for patients with COPD. These programme elements are similar to those utilised in the studies reviewed which demonstrated effects on health outcomes for patients with COPD. It could therefore be argued that it would be reasonable to assume that the Liverpool PR self-management education strategy could effect similar changes in health outcomes or COPD patients enrolled in the programme.

Experiential and Practice Based Learning

Experiential and practice-based learning is the acquisition of skills from life experiences and/or hands-on training on these experiences such as symptom monitoring, symptom management, medication use and exacerbation management. Hesselink et al. (2004) found that a self-management education programme using experiential learning techniques produced better inhalation techniques, although the same programme resulted in only small differences in disease symptoms and did not effect any change in HRQoL. Two other studies (Sedano et al., 2009; Fan et al., 2012) that used experiential or practice based learning demonstrated that improved health behaviours such as medication efficacy through optimised inhaler technique or appropriate antibiotics or steroid use has been linked with improved self-management, symptom control and healthcare utilisation. Following the review of these three studies, it would be reasonable to suggest that self-management education using experiential and practice based learning strategies may effect change in health behaviours in patients with long term conditions. These changes in health behaviours can include improved medication efficacy, symptom monitoring, symptom management or control and healthcare utilisation. The Liverpool PR self-management education strategy also incorporates similar elements such as practical symptom management, medication management including inhaler techniques, symptom identification and symptom management skills training that is tailored to each patient's needs. Based on the trends identified from the results of the literature review, the Liverpool PR self-management education strategy

should be able to produce similar effects on health outcomes on COPD patients enrolled on the programme.

4.8.2 Self-Management Education Evaluation of Outcomes

The effects of self-management education have to be evaluated in order to ascertain the impact of the intervention. The findings of the literature review identified common health outcomes used to measure the effect of self-management strategies. These outcomes included:

- adherence and self-care behaviour
- COPD symptoms and symptom management
- disease knowledge
- emotional functioning
- functional capacity – activities of daily living, walking distance
- healthcare utilisation and cost
- health related quality-of-life/health status
- self-efficacy.

Adherence and Self-Care Behaviour

The aim of self-management education as part of PR was outlined by Evans and Morgan (2007) as being to instil a sustained lifestyle change in this patient group and this can be done by developing patients' coping skills to maintain as active a lifestyle as possible. These coping skills included, promoting the correct use of drugs and encouraging the early identification of increasing symptoms heralding an exacerbation, so that the symptoms can be treated early. The development of these health-related behaviours has been shown to be affected by factors such as the patient's knowledge, emotional adjustment to illness, self-efficacy, motivation, self-management skills, social support, environmental obstacles and ongoing support (Wortz et al., 2012).

The Efraimsson et al. (2008) study showed significant effects of the COPD self-management educational intervention on patients' quality-of-life, smoking cessation and knowledge about their disease. Patients in the intervention group reported a reduction in respiratory distress symptoms, increased physical activity and improved psycho-social health as well as disease knowledge. Their findings showed that conventional care alone did not have an effect on patients' QoL and smoking habits. Instead, the evidence suggests that a structured programme with self-management education is needed to motivate patients for life-style changes, which supports previous findings and recommendations in clinical guidelines. Sedano et al. (2009) found that their COPD self-management programme led to changes in patient behaviour with more than 50% of

patients promptly self-treating their exacerbations with antibiotics and prednisolone. This appropriate adoption of self-management was associated with a reduction in hospital admissions and emergency visits. Khdour et al. (2009) also demonstrated significant improvement in patient adherence with clinical regimen post self-management education intervention.

The impact of self-management education on self-care behaviours such as smoking cessation, effective symptom monitoring, proactive symptom management and life style change is clear in these studies reviewed: Overall, the results clearly indicate a positive effect on self-care behaviours in patients with long term conditions. According to NICE (2004, 2010), PR process should incorporate a programme of physical training, disease education, nutritional, psychological and behavioural intervention: The Liverpool PR self-management education strategy incorporates bespoke behavioural intervention and coaching to encourage or facilitate lifestyle change through smoking cessation, healthy diet and commitment to exercise and adherence with medical management of their COPD. The results of the literature review indicate that similar strategies to the Liverpool PR self-management education strategy can effect change in health outcomes for patients with COPD, therefore enabling hypothesis that the Liverpool PR self-management education strategy should be able to effect similar changes in COPD patients enrolled on the programme.

COPD Symptoms and Symptom Management

Effective symptom management, which includes symptom awareness, symptom monitoring and proactive action planning has been identified as an essential component of effective self-management in long-term conditions. The primary effects of appropriate symptom monitoring include, the appropriate use of respiratory medication (Bourbeau et al., 2003, Sedano et al., 2009 and Fan et al., 2012), improved disease symptoms (McGeoch et al., 2006; Khdour et al., 2009; Trappenburg et al., 2011 and Wakabayashi et al., 2011), reduced symptom impact (McGeoch et al., 2006), reduced patient symptoms (Efraimsson et al., 2008 and Khdour et al., 2009) and improved patient adherence (Khdour et al., 2009). The secondary effects of effective symptom monitoring include, reduction in hospital admissions for acute exacerbations of COPD (Bourbeau et al., 2003 and Khdour et al., 2009) and reduced healthcare costs (Bourbeau et al., 2006). The overall findings of these studies indicate that self-management education can improve symptom management in patients with long-term conditions. Similar self-management education strategies utilised within the Liverpool PR programme indicates that similar effect on health outcomes as those found in the literature review should be possible to achieve with the Liverpool PR self-management education strategy.

Disease Knowledge

Disease specific knowledge is another vital component of effective self-management in long-term conditions. Although one study could not demonstrate an improvement in COPD knowledge (Fan et al., 2012), it is important to consider that this study was terminated early due to a high mortality rate and, of the four other studies that reviewed disease knowledge as an outcome measure (McGeoch et al., 2006; Efraimsson et al., 2008; Khdour et al., 2009 and Wakabayashi et al., 2011), all demonstrated significantly improved disease knowledge post self-management education. These findings suggest that, the link between self-management education and improved disease knowledge is clearly established in these studies. What is still unclear is if improved disease knowledge is associated or translates into improved self-management ability in patients post self-management education, assuming that these factors should both inform and influence health behaviours. The Liverpool PR self-management education strategy includes a comprehensive disease education component consisting of anatomy, physiology, pathology, disease aetiology and associated symptom management. The fully comprehensive nature of this strategy ensures that patients attending the programme can acquire a robust knowledge base about their condition and management options available to support COPD patients in Liverpool. The results of the literature review indicate that similar strategies to the Liverpool PR self-management education strategy can effect change in disease knowledge, therefore supporting the hypothesis that the Liverpool PR self-management education strategy should be able to effect similar changes in COPD knowledge in patients enrolled on the programme.

Emotional Functioning

The impact of COPD reaches beyond the physical for many patients, consequently, dyspnoea related anxiety, health-related anxiety and depression are common among this patient group. The conceptual framework for COPD self-management suggests that content of COPD self-management support should focus on addressing patients' fears associated with the uncertainty, progression and suffering of their disease, their expectations about overcoming or replacing losses, their needs for improved health literacy and their desire for improved care (Wortz et al., 2012). Only two (15.4%) out of the 13 studies in the literature review evaluated emotional functioning as a health outcome and neither demonstrated a change effect: Trappenburg et al. (2011) also observed no change in emotional functioning post self-management education and McGeoch et al. (2006) found no statistically significant difference in anxiety or depression following self-management education. The results of the literature review suggest that self-management education programmes may have little or no effect on emotional functioning in patients with COPD. These results indicate that similar self-management

education components used to address emotional dysfunction in patients enrolled on the Liverpool PR programme may not effect statistically significant change in emotional functioning within this patient group.

Functional Capacity

Functional capacity in COPD is a complex issue to evaluate as the issues that affect functional capacity are usually multi-factorial and difficult to isolate. However, functional capacity is a useful tool to assess the impact of disease, symptom severity and treatment effect. The rationale behind this is that, COPD causes shortness of breath, which in some cases can be severe; as a result, many individuals with COPD develop a lack of confidence regarding their ability to avoid breathing difficulty while participating in certain activities, however minimal the physical demands of the activity may be. This lack of confidence may be expressed as low self-efficacy. As a result of low self-efficacy, COPD patients may refrain from many routine activities of daily living. Identifying situations in which individuals with COPD experience low self-efficacy would allow the development of specific treatment interventions designed to increase the patient's self-efficacy in these situations and consequently increase activity (Wigal et al., 19991) through improved knowledge, symptom monitoring skills, symptom management skills and action plans for different scenarios the patient may face. In turn, the increase in patient activity levels can reverse the debilitating effects of physical deconditioning in COPD, improve confidence and psychomotor functioning, therefore improving quality-of-life, specifically, health-related quality-of-life.

Only three studies (23.1%) evaluated functional capacity and the results were inconclusive: Bourbeau et al. (2003) found walking distance did not change significantly within or between groups, Monninkhof et al. (2003) found no significant differences in walking distance and Wakabayashi et al. (2011) demonstrated significant and sustainable improvement in instrumental activities of daily living. The physical training aspect of the Liverpool PR programme focuses on practical functional capacity, i.e., physical activity linked closely with activities of daily living that each patient finds difficult. The bespoke physical training programme is delivered in conjunction with a bespoke self-management education programme. The self-management education includes components that link anatomy, physiology and pathology to appropriate coping strategies such as pacing techniques, symptom monitoring with self-monitoring tools such as the Borg Dyspnoea Scale to enable patients to effectively assess, manage and monitor physical activity and training as well as improve their confidence to carry out physical activities or physical training. Physical training has been associated with improved functional capacity relating to activities of daily living in several studies and in

this literature review, Wakabayashi et al. (2011) demonstrated significant and sustainable improvement in activities of daily living following self-management education. It is therefore possible to hypothesise that a combination of physical training and self-management education intervention used in the Liverpool PR programme may effect change in COPD patients enrolled on the programme.

Healthcare Utilisation and Cost

Inappropriate healthcare utilisation such as the use of emergency healthcare resources for non-urgent or routine clinical intervention is one of the main causes of high healthcare costs in long-term condition management (Siddique et al., 2012; Bourbeau et al., 2006; Bourbeau et al., 2003). Due to the high cost of poorly managed COPD, the earlier studies in this literature review focused on the impact of self-management education on healthcare utilisation, cost and resources: Gallefoss and Bakke (2000) established that self-management education reduced the need for GP visits and kept a greater proportion of patients independent of their GP. Bourbeau et al. (2003, 2006) reported significant reduction in hospital admissions, frequency of admissions and length of stay in hospital in patients with COPD following a structured self-management education and exercise programme. Later studies also demonstrated similar trends: Trappenburg et al. (2011) found that COPD self-management education intervention improves health status recovery, reduced the number and frequency of exacerbations. Wakabayashi et al. (2011) found that comprehensive multicomponent COPD education strategy demonstrated a significant reduction in the number of hospital admissions during the period of integrated education. Fan et al. (2012) reported findings that imply that self-management education reduces the incidence of COPD related hospitalisations and is associated with appropriate treatment of exacerbations.

Optimised self-management in chronic disease can be linked with altered health-related behaviours, including appropriate use of medication and other healthcare utilisation such as emergency medical intervention or rescue medication use. This change in behaviour in turn often can result in reduced overall management costs per patient: Bourbeau et al. (2006) also demonstrated the mean healthcare cost per COPD patient was $3,338 lower for patients following self-management education intervention. Bearing the findings of this literature review in mind, it would not be unreasonable to surmise that effective symptom monitoring, appropriate action planning and robust support network as part of a self-management education strategy has been shown to reduce the incidence of inappropriate healthcare utilisation. It would therefore not be unreasonable to assume that a similar strategy utilised within the self-management education

component of the Liverpool PR service may effect similar change in healthcare utilisation and cost.

Health Related Quality-of-life

The theoretical principles of self-management suggest that changes in HRQoL may be affected by the stability of the patient's condition: Self-management education theory such as the Bandura theory links improved symptom management, improved sense of well-being and self-efficacy with improvement in HRQoL in patients with long term conditions (Bandura, 1977). The studies that evaluated HRQoL revealed conflicting results: Gallefoss and Bakke (2000) demonstrated a link between HRQoL and frequency of GP visits with increasing number of GP visits being associated with decreased HRQoL. Efraimsson et al. (2008) demonstrated significant improvement in HRQoL post self-management education intervention. Khdour et al. (2009) demonstrated significant improvements in overall HRQoL and specifically relating to disease symptoms and disease impact. On the other hand, post self-management education intervention, both Hesselink et al. (2004) and McGeoch et al. (2006) found no statistically significant difference in HRQoL and Trappenburg et al. (2011) found no change effect in HRQoL. The differences observed may be due to the differences in self-management programme content and delivery across the different studies.

Self-Efficacy

Self-efficacy is an individual's perceived ability to manage or succeed in certain circumstances. According to Bandura's Theory, self-efficacy can inform health-related behaviours that in turn can then determine the overall management of that condition, for example, lifestyle related choices such as smoking, exercise and diet are dependent on an individual's self-efficacy. One of the key predictors of successful behaviour change is confidence (self-efficacy) in the ability to carry out an action and the expectation that a particular goal will be achieved (Bandura, 1977). Increasing self-efficacy is seen as a prerequisite for behaviour change to improve disease self-management, which in turn may influence individual health and healthcare use (Foster et al., 2009). These findings suggest that, self-efficacy and self-management go hand-in-hand and neither can exist without the other: Three studies (23.1%) evaluated self-efficacy; Monninkhof et al. (2003) found that there was no significant difference in patient self-efficacy between control and intervention groups. Hesselink et al. (2004) demonstrated significantly improved medication related self-efficacy post self-management education. Trappenburg et al. (2011) reported statistically significant improvement in exacerbation related self-efficacy post self-management education. The findings of this literature review indicate that multi-component self-management education intervention can

improve self-efficacy. It is therefore logical to anticipate that similar components in the Liverpool PR self-management education programme should be able to effect similar change using a similar strategy.

4.9 IMPLICATIONS FOR THE THESIS

The findings of this literature review demonstrated that multicomponent and health professional-led self-management strategies for COPD similar to the Liverpool PR strategy can result in improved health outcomes for patients with COPD. It is therefore reasonable to assume that the Liverpool PR strategy may have the same impact on health outcomes in COPD patients enrolled on the programme. The common outcomes used to measure the effect of these self-management strategies included COPD symptoms and symptom management, disease knowledge, emotional functioning, functional capacity, healthcare utilisation, Health Related Quality-of-life/Health status and self-efficacy.

Reviewing the results of this literature review was used to inform the design of the final study in this thesis. The findings of this literature review support the hypothesis from the retrospective analysis of Liverpool PR health outcomes, i.e., that the Bristol COPD Knowledge Questionnaire (BCKQ) may not be an adequate measure of self-management ability. This could be due in part to the nature of the BCKQ, in ascertaining patient knowledge values which is only part of attaining clinical self-management - the others being self-efficacy, emotional adjustment to illness, motivation, self-management skills and psychosocial support.

The implications of this finding, is that an alternative evaluation tool to establish a baseline and ascertain the treatment effect would be required to evaluate the impact of the Liverpool PR self-management education strategy in conjunction with the BCKQ. The secondary purpose of this literature review was to identify alternative measures of self-management that were validated, simple to administer, practical to incorporate into the PR assessment process and be of low burden to the COPD patients who had volunteered to participate in the study. There were also contractual and logistical limitations bear in mind with regard to gaining access to information such as, patients' admission data, GP visit data and other healthcare utilisation information. These access issues meant that the PR team were not able to gain access to this information and because patient reported versions of this data was often inaccurate or incomplete, these measures were therefore not included in the design of the prospective study. In consultation with the Liverpool commissioners and the PhD supervisory team, the Understanding COPD questionnaire – UCOPD (O'Neil et al., 2012; Cosgrove et al.,

2013) and the Chronic Disease Self-Efficacy Scale – CDSES also referred to as the Self-Efficacy for Managing Chronic Disease 6-Item scale (Lorig et al., 1996) were chosen as the generic and disease-specific evaluation tools for the next study: The findings of the literature review demonstrated that measures or indicators of self-management such as, patient adherence or self-care behaviour, COPD symptom management, disease knowledge, emotional functioning, functional capacity, healthcare utilisation or costs, health related quality-of-life and self-efficacy improved with COPD self-management intervention. The process of selecting an appropriate measure for self-management required careful consideration of three main factors:

1. how these measures or indictors of self-management could be measured
2. ease of administration
3. burden on the patients

The UCOPD covers aspects of disease knowledge, symptom monitoring, exacerbation management and emotional functioning that were identified from the findings of the literature review as measures of self-management. Although more generic, the CDSES also covers similar aspects in its construct. During this process, the Six-Minute Walk Test (6MWT) has been proven to be a valid measure of functional capacity in this review as has the Hospital Anxiety and Depression Scale (HADS) for emotional functioning. As a result, the 6MWT and HADS will be used to further evaluate the impact of the Liverpool PR self-management education strategy for COPD patients attending the Liverpool PR programme.

4.10 LIMITATIONS

The main study limitation was use of the single reviewer during study selection and data extraction, due to resources constraints, as this was a research degree. This potentially increases the risk for selection bias during the screening and selection processes (Hegedus and Moody, 2010) and information bias during the detailed article reviewing process or during the reporting of the study findings (Althubaiti, 2016). However, the importance of this may be reduced given the intention of the review, not to synthesise the overall effect of self-management but to help further understand the findings of the research student's previous study. Furthermore, using a standardised quality assessment proforma may have helped to reduce potential bias. The other major limitation of the review was that none of the studies were undertaken in a PR setting, and no such study was identified. Therefore, this may limit the generalisability of the study findings to the context of the thesis because the types of patients and the severity of their disease may differ.

4.11 IMPLICATIONS FOR FURTHER RESEARCH

Self-management education can effect change and therefore impact on health outcomes in patients with COPD; although the body of evidence for COPD is comparatively new and still evolving, this hypothesis is supported by the findings of this literature review and a Cochrane intervention review of self-management education for patients with COPD by Effing et al. (2009). Effing et al. (2009) concluded that self-management education is associated with improvement in quality-of-life and a reduction in hospital admissions with no indications of detrimental effects in other outcome parameters. However, because of heterogeneity in interventions, study populations, follow-up time, and outcome measures, the findings from analysis of the data was insufficient to formulate clear recommendations regarding the form and contents of self-management education programmes in COPD. The resultant recommendation was that clear benchmarks needed to be specified by authoritative bodies about outcome measures and length of such studies. In addition, future research studies with sufficient sample size and longer follow-up time focusing on the acquisition of self-management skills and behavioural change as well as the definition of the effective elements of self-management programmes are needed to further investigate this area. To date there has not been a study to explore self-management education strategies in an active PR environment in the NHS and this review will serve to provide useful data to inform the design of further studies to investigate this aspect of COPD management.

4.12 CONCLUSION

In this chapter, a literature review of self-management education strategies and outcome measures demonstrated the ability of COPD self-management education strategies similar to that utilised in the Liverpool PR service to effect change in clinical outcomes and self-management measures in patients with COPD. These findings seem to suggest that the lack of correlation observed in the retrospective analysis of Liverpool PR health outcomes was unlikely to be due to the self-management education strategy being used and may be due to the suitability of the measure of self-management that was being used. In the next chapter, a prospective study carried out using additional measures of self-management identified from the literature review will be described and the findings discussed.

CHAPTER FIVE

A PROSPECTIVE STUDY OF THE EFFECTS OF SELF-MANAGEMENT EDUCATION ON PATIENT HEALTH OUTCOMES

5.1 INTRODUCTION

In the previous chapter, the overall findings of a literature review suggest that self-management education can improve patient adherence with clinical regimens and self-care behaviours, improve COPD symptom management, increase disease knowledge, increase functional capacity, reduce healthcare utilisation and cost, improve health related quality-of-life and improve self-efficacy. However, some of the results were conflicting, and there appeared to be no effect on emotional functioning. The findings of the literature review were inconsistent with the findings of the retrospective analysis of routinely collected Liverpool PR data which showed no relationship between disease knowledge using the Bristol COPD Knowledge Questionnaire (BCKQ) and the other clinical outcomes or change in disease knowledge with change in clinical outcomes. Based on these findings, it was impossible not to query if the lack of correlation could be due to an ineffective self-management education strategy or whether the BCKQ is not an appropriate measure of self-management. As part of the literature review, the research student was able to demonstrate that the strategy utilised in the Liverpool PR programme is similar to self-management education strategies that were observed in the studies in the literature review and should therefore be able to have a similar effect on patients attending the PR programme, if randomised controlled trial findings are replicable in routine practice and within a PR setting. Following on from the retrospective study, the logical progression was to explore the appropriateness of self-management assessment tools. The studies in the literature review used a range of assessment tools and based on ease of interpretation, burden on the patient and clinical relevance, a generic self-efficacy tool (Chronic Disease Self-Efficacy Scale - CDSES) and a disease specific tool (Understanding COPD Questionnaire - UCOPD) were chosen to be used in addition to the BCKQ (used as part of routine clinical practice) to explore the impact of the COPD self-management education component of the Liverpool Heart and Chest NHS Hospital's PR programme on health outcomes for COPD patients attending the PR programme in this prospective study.

5.2 REFLECTION ON THE RESEARCH JOURNEY

Between 2012 and 2013, several studies into the concept of self-management added to the evidence base available for self-management in COPD. Although this served to improve my insight into the concept of self-management in the context of COPD patient management, to me there still were gaps and inconsistencies in the evidence to form a

firm opinion on the definition, make up and intervention effect of self-management for COPD patients in PR settings. My "lightbulb moment" was not one that answered the questions and queries I had about self-management in PR for COPD patients, instead it seemed to be a signpost to guide the next phase of my exploration of this subject. This signpost was inspired by the observations I made about the evidence I had been reviewing which had outlined the impact of self-management programmes on health behaviours and some outcome measures such as functional capacity and emotional functioning. However, there appeared to me that there was no information about what I can only describe as the "cognitive" aspects of self-management, i.e., knowledge, understanding and self-efficacy or confidence. There was a lack of evidence about these three factors, not only in COPD but also in well-established evidence bases on other chronic diseases such as asthma and diabetes: I questioned what these elements looked like in the PR patient group and if these were subject to change following PR intervention. I also began to query the mechanism(s) that enabled COPD patients to develop self-management skills? Where these three factors part of self-management? Did they relate to each other and if they did, how did they relate to each other? Did they relate to other outcomes better than the BCKQ had done in the retrospective analysis of the PR outcomes data?

5.3 THE LIVERPOOL PR SERVICE – CHANGES IN PRACTICE

Before proceeding with outlining the next study in this thesis, the changes to the PR programme in which the study was undertaken are outlined. As previously described in Chapter Two (see Pages 46 - 77), PR is an exercise and education based programme of intervention for patients with chronic lung disease, predominantly, COPD. In Liverpool, this programme is provided by the Liverpool Heart and Chest Hospital and commissioned by the Liverpool Clinical Commissioning Group (LCCG). The referral and triage process for this study remains unchanged from the process described for the retrospective study (see Chapter Two, Pages 49 - 50). Clinical practice within PR remained unchanged from the process described in Chapter Two (see Pages 50 - 55), except for the assessment of functional capacity and the three-month follow up review. Originally, to measure functional capacity, the ISWT was used routinely, with the 6MWT used only for patients with significant physical impairments or the need for a mobility aid. This made the comparisons of baseline and post intervention values challenging and based on recommendations from the retrospective study and confirmed from evidence in the literature review, the measure for functional capacity was standardised to the 6MWT as the single measure for functional capacity across all PR sites in Liverpool. The 6MWT was chosen instead of the ISWT for practical reasons, as it can be applied to all patients, whereas the ISWT may be more suitable to more functionally able patients

(Alison et al., 2009; Singh et al., 2014). The second change made was that the three-month follow up review was removed from the PR Service Model (see Figure 5.1 for Current PR Service Model). This change was made following the review of the findings of the retrospective study which showed that changes in the clinical outcomes (functional capacity, respiratory disability, anxiety, depression and self-management) were sustained over time, but that no further improvements in health outcomes were observed post intervention, except in depression levels, which continued to improve. Resources were focused instead on the development of post PR intervention strategies to sustain the benefits achieved from attending PR rather than attending a further follow-up appointment post completion of the programme. Hence patients in the PR programme are now assessed only once, immediately post completion of the programme. Although the literature review suggested no change in emotional outcomes following self-management education, the previous retrospective study had shown this changed over time and therefore the HADS was retained as an assessment.

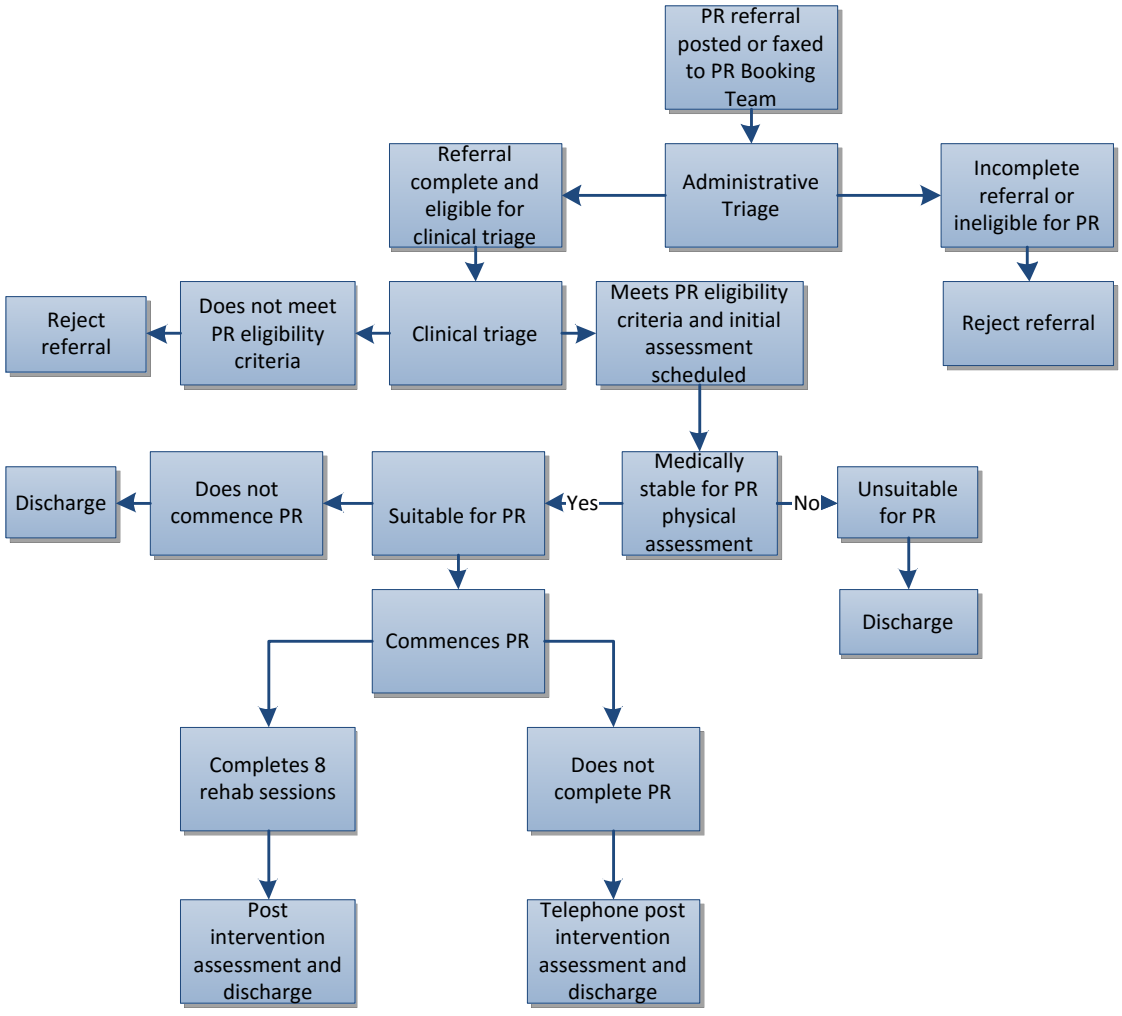

Figure 5.1 – Current PR Service Model

5.4 METHODOLOGICAL APPROACH

The findings of the survey (Chapter Two) demonstrated that the format of the Liverpool service was typical of similar services in the North West of England. Retrospective analysis of health outcomes (Chapter Three) showed that self-management, functional capacity, emotional functioning and respiratory disability improved post PR intervention, but there was a lack of a significant relationship between self-management and the other health outcomes measured. The results raised questions about the suitability of the self-management approach utilised and/or the tool used to evaluate self-management. The literature review on self-management education in COPD (Chapter Four) demonstrated that similar self-management approaches could effect changes in the health outcomes and suggested appropriate measures both of self-management and of likely health outcomes.

Based on these findings, a simple prospective longitudinal study was designed to evaluate the intervention effect on measures of self-management and health outcomes for COPD patients attending the Liverpool PR programme using the outcome measures identified. A prospective study as a study that follows cases forward in time, measuring attributes at multiple time points and change is measured by examining differences between each time point or study wave (Jupp, 2006). A simple longitudinal study design involves one group, pre-intervention measurement on the outcome variable(s), one intervention where everyone receives the same treatment and post intervention measurement on the outcome variable(s) (de Vaus, 2005).

This study design was deemed as the most suitable method to evaluate the change in measures of self- management and of health outcomes post Liverpool PR intervention. Other quantitative prospective study designs such as an experimental study design or cohort studies were discarded primarily because the same intervention was being applied across the study group without a control to compare the different interventions (de Vaus, 2005). The need for a control (or comparator) group was not considered as a priority for this study as its main aim was to explore the intervention effect on health outcomes and the relationships between the outcome measures as part of the treatment or intervention development phase. A cross-sectional study design, which measures processes or outcomes at one single point in time, was also discarded because the purpose of the study was to explore the change in self-management and health outcomes post PR intervention.

5.5 STUDY OBJECTIVES

The objectives of this study were:

1. To estimate levels of COPD self-management using the Bristol COPD Knowledge Questionnaire (BCKQ), the Understanding COPD Questionnaire (UCOPD) and the Chronic Disease Self-Efficacy Scale (CDSES) at baseline and post PR intervention.
2. To explore relationships between the BCKQ, the UCOPD and CDSES.
3. To estimate changes in levels of the BCKQ, UCOPD and CDSES between baseline and post PR intervention.
4. To explore the relationships between changes in the BCKQ, changes in the UCOPD and changes in the CDSES.
5. To explore the relationships between changes in the BCKQ, UCOPD, CDSES and changes in functional capacity using the Six Minute Walking Test (6MWT), respiratory disability using the MRC dyspnoea scale (MRC) and emotional functioning using the Hospital Anxiety and Depression Scale (HADS).

5.6 STUDY DESIGN

5.6.1 Study Population

The study population consisted of patients with COPD commencing the Liverpool PR programme at the Liverpool Heart and Chest NHS Hospital. The inclusion criteria for this study were as follows:

1. Patient with a confirmed diagnosis of COPD prior to referral.
2. Patient with a community-based dwelling.
3. Patient deemed to have mental capacity to make informed consent to participate in the study.
4. Patient assessed as being medically stable with a cardiovascular status eligible to participate in the exercise component of the programme and has completed the PR baseline assessment.

5.6.2 Identification of Study Population

Potentially eligible patients for this study were identified by the research student (who was also the Clinical Lead for the PR service at the time of the study) at the clinical triage stage using the information documented on the PR referral form to assess patient eligibility according to the study inclusion criteria (see Figure 5.2 for the Study Flowchart).

5.6.3 Recruitment Process

Each eligible patient was sent an invitation to participate in the study (see Appendix 21) and a study information sheet with a brief explanation of the study (see Appendix 22)

with their PR appointment letter. At the start of the PR assessment clinic, each eligible patient was asked by the assessing clinician if they were interested in participating in the study. If they were, the study was then explained to the patient, they were given a study information sheet (see Appendix 22) and formally consented (see Appendix 23 for consent form) if deemed medically fit to participate in the PR programme. Each study participant was offered the opportunity to be kept informed of the outcome of the study via a newsletter. Patients who accepted this offer filled out a form declaring this interest (see Appendix 24) and this form was stored with the research copy of the consent form.

5.6.4 Setting

Study participants were recruited from all PR clinics (seven community-based clinics and one hospital-based clinic) by the same group of clinical staff from the Liverpool Heart and Chest NHS Hospital (see Figure 5.2 for Study Flowchart and Figure 5.3 for the study process).

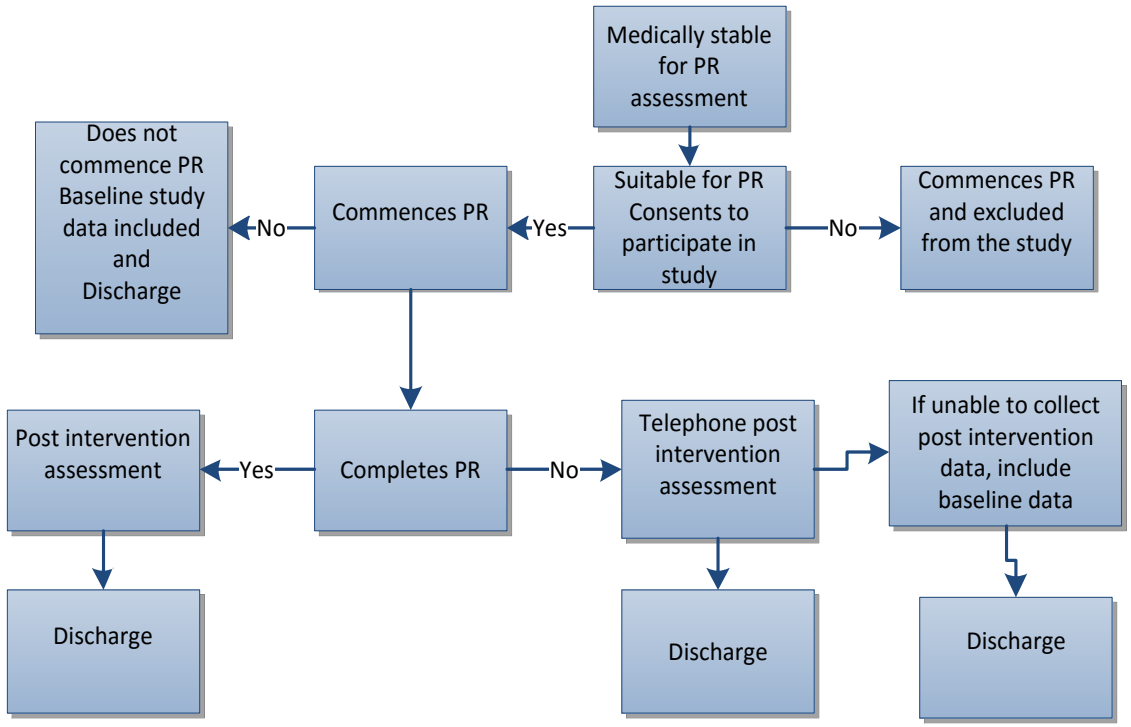

Figure 5.2 – Prospective Study Flowchart

Figure 5.3 – Study Process Mapped Against PR Clinical Stages

5.6.5 Calculating Sample Size and Recruitment

The target was to recruit 301 participants in order to obtain baseline and post-intervention information from at least 157 participants to enable the correlations to be estimated to within ±0.15 with 95% confidence. The referrals, attrition and programme completion data from the 2013 – 2014 financial year were used to estimate and calculate a realistic sample available for this study. Data extracted from the Patient Administration System and the PR outcomes database on the 31/01/2015 showed that during that year, 563 PR referrals were received, of whom 126 (22.4%) referrals were not eligible for the programme or declined due to the form being incomplete. The remaining 437 (77.6%) patients were offered an initial assessment with 385 (68.4%) initial patient assessments being carried out. Two hundred and sixty-three patients (46.7%) were considered to be cardiovascularly stable and hence, able to complete the PR initial assessment. Out of these, 232 (41.2% of referrals, 88.2% of those completing the initial assessment) started the programme. Of the 232 who started PR, 172 (30.6% of referrals, 74.1% of those eligible to participate in PR) completed the programme of which 103 attended all 10 sessions and 69 were categorised as completed based on meeting the goals set for PR.

During 2014, the number of referrals had increased, meaning that the annual referral rate increased to 1380; it was anticipated that this referral rate would be maintained through the recruitment period for this study. Previous research and audit projects among this patient group have proved to have very high consent rates: The COPD Patient Reported Measures (PREMs) pilot in conjunction with the British Lung Foundation, the Royal College of Physicians and the Healthcare Quality Improvement Partnership in June 2014 had a 100% consent rate. The pilot for the annual British Thoracic Society's COPD audit in August 2014 also had a 100% consent rate. In view of this pattern, it was deemed reasonable to estimate at least an 80% consent rate for this study.

Seven months of recruitment was available within the scope of the PhD programme. During the recruitment period, we estimated that approximately 805 patients would be referred. Based on the estimates above, we were able to assume that at least 46.7% of these participants would be cardiovascularly stable and eligible for the study and that at least 80% of eligible participants would consent to take part in the study. Therefore, we could expect that 301 patients would start the study of whom at least 195 (65%) would complete PR intervention (and, hence, likely to complete the post-intervention research assessment). We estimated that the minimum target sample size of 157 could be achieved with a post-intervention follow-up rate of 52.2% (or greater).

5.6.6 Self-Management Measures

There were three main outcome measures used in this study, the BCKQ which was part of the routine PR outcome measures (see Appendix 4) and two study questionnaires (the UCOPD and the CDSES - see Appendices 25 and 26). The BCKQ as previously described in Chapter Two (Pages 54 - 55) is a multiple-choice questionnaire designed to assess COPD knowledge. The range of scores for the BCKQ is 0 – 65, with a higher score indicating better disease knowledge. The other two measures of self-management used in this study were chosen as a result of the findings of the literature review in the previous chapter. Both were chosen based on their method of administration, scoring method, burden on the patient and clinical relevance to the COPD patient population. The UCOPD questionnaire (Section A) is an eighteen-item disease specific questionnaire that assesses disease understanding, self-efficacy and use of key self-management skills in patients with COPD (O'Neil et al., 2012 - see Appendix 25). The method of administration is by a written questionnaire and the burden on the respondent with the UCOPD questionnaire is low. Each section is also evaluated using a numeric scale ranging from 0 – 10 (not confident to very confident). It has good validity and practical properties, and readability was acceptable. It has good test-retest reliability (ICC range: 0.87 to 0.96, Wilcoxon: $p > 0.05$) and internal consistency (Cronbach's Alpha range: 0.78 to 0.95). It is responsive to pulmonary rehabilitation (O'Neil et al., 2012). The algorithm to calculate the score for the UCOPD is as follows: UCOPD = sum of scores/180 x 100. The range of scores for the UCOPD is 0 – 100, with a higher score indicating better understanding of COPD and its implications.

The CDSES questionnaire used in this study is a six-item questionnaire (see Appendix 26) that evaluates perception of confidence and self-management in patients with chronic diseases (Lorig et al., 1996). Items on the 6-item scale pertain primarily to performance accomplishment rather than behaviour ("keep various symptoms from interfering with things you want to do"). The method of administration is by a written questionnaire and the burden on the respondent is low due to its brief nature combined with a relatively low reading level requirement. The administrative burden is also low as no training is required to administer the CDSES. Each question has a numeric scale ranging from 1 – 10 (not at all confident to totally confident) in managing that specific aspect of their disease. There are no population-based norms or cut-off scores for the CDSES. Sensitivity to change is not addressed in the CDSES documentation, although intervention studies do show changes in self-efficacy scores and the internal consistency coefficient for the 6-item shortened scale was reported as 0.91 and test–retest correlations were 0.82–0.89 for the different subscales (Brady, 2011). The range of scores for the CDSES is 1 – 10, with a higher score indicating better self-efficacy.

5.6.7 Clinical Outcome Measures

The clinical outcome measures considered in this study were as follows:

- Six Minute Walk Test (6MWT) to measure functional capacity
- MRC Dyspnoea scale as a measure of respiratory disability
- Hospital Anxiety and Depression Scale (HADS) as a measure of emotional functioning

The clinical process of carrying out the 6MWT was described in detail in Chapter Two (Pages 52 - 53) but, in essence, the 6MWT (see Appendix 2) requires the patient to walk at their own pace between two cones, set nine meters apart to allow for a total walking distance of 10 metres for a total of six minutes with the choice to stop, rest or terminate the test at any stage during the period of the test (Alison et al., 2009). Holland et al. (2014) and Singh et al. (2014) describe the 6MWT as a reliable measure of functional capacity in patients with COPD. A measure of functional capacity was a also a requirement of the service level agreement for this commissioned PR programme and the simplicity of the test in terms of few equipment being required to run the test were additional reasons for the choice of this particular outcome measure.

The Medical Research Council (MRC) dyspnoea or breathlessness scale (see Chapter Two, Page 53 for detailed description) comprises five statements that describe almost the entire range of respiratory disability from none (Grade 1) to almost complete incapacity (Grade 5). This outcome measure was important clinically in enabling the assessing clinician to evaluate the severity of a patient's breathlessness levels and was also a requirement of the service level agreement.

The Hospital Anxiety and Depression Scale (HADS) as previously described in Chapter Two (Page 54) is a brief self-assessment scale developed to detect states of anxiety and depression. Scores for each subscale for anxiety (HADS-A) and depression (HADS-D) range from 0 to 21 with scores categorised as normal 0–7, mild 8–10, moderate 11–14, and severe 15–21 (see Appendix 3). The improvement in HADS was maintained in the short term in this study, despite the literature review suggesting that self-management did not affect this outcome, because both subscales improved over time in this patient group in the retrospective study. In addition, depression and anxiety are highly prevalent in patients with COPD (Yohannes, Baldwin and Connolly, 2000; Van Manen et al., 2002; Kunik et al., 2005; Puhan et al., 2008). There is general agreement that this common comorbidity should be addressed in order to improve patients' health-related quality of life and to lower health care consumption (Dahlen and Janson, 2002; Fitzgerald et al., 2007; Puhan et al, 2008). Therefore, including the address of these symptoms as part

of the rehabilitative process and measuring the change at the post intervention stage are not only important clinically, but is required as part of the service level agreement with the Liverpool commissioners.

5.7 DATA COLLECTION

5.7.1 Baseline Assessment

Once the patient had opted to participate in the study, the assessing clinician handed out the study documentation pack which the study participant was asked to complete. This pack consisted of a study front sheet (see Appendix 27) and the two study questionnaires, i.e., the UCOPD questionnaire and the CDSES questionnaire. On completion of the initial PR assessment, each study participant was given a programme start date for their rehabilitation sessions.

5.7.2 Follow-Up Assessment

On completion of the rehabilitation sessions, a post-intervention assessment was scheduled for the patient. The research student flagged patients who were returning for a post-intervention assessment with the clinics. The assessing clinicians then handed out a study documentation pack to every patient who had previously agreed to take part in the study. The assessing clinician recorded the study number found on the consent form in the clinical records on the post-intervention study documentation pack. Once the routine PR post-intervention assessment had been completed, study participants were asked to fill out the study questionnaires (the UCOPD and CDSES).

5.7.3 Other Data

Data from routine clinical assessments at baseline and post-intervention was extracted from the PR database using the patient's hospital number and merged with the study data. This data included patient demographic information collected using a combination of patient self-reported information and clinical information from the referral form, which is routinely recorded on the PR database; explanatory variables such as age, gender, smoking status and respiratory disability status.

5.7.4 Follow Up of Non-Completers

Participants who did not complete the programme were screened through the Patient Administration System (PAS) to check their names against the death register. Those who were alive were sent a routine DNA letter asking them to contact the clinicians at the PR clinic. In addition, they were contacted by the research student by telephone 16 weeks after commencing the programme to arrange study follow-up or to conduct a telephone assessment using the PR and study questionnaires. Participants who did not

respond to the routine DNA correspondence from the team or telephone contact on two occasions from the research student regarding their attendance and participation in the study, had their baseline data included in the study database and their consent at their initial assessment upheld. The non-completers who were contactable and deemed too unwell to continue with the programme were classified as Unable to Attend (UTA) and a clinical decision was made to not to make further contact to arrange study follow-up.

5.8 DATA MANAGEMENT

5.8.1 Baseline Assessment Data Management

The completed study documentation pack from the baseline assessment was handed to the research student at the end of the clinic. In the absence of the research student, the pack was stored in a secured cabinet which was accessed by the research student for review and data inputting on her return. The dataset for each participant, including routinely collected PR health outcomes data, the UCOPD and CDSES scores was recorded on a separate study database by the research student. The study questionnaires were then stored separately from the routine PR records in a locked cabinet in the Therapies Department.

5.8.2 Follow-Up Assessment Data Management

The post-intervention study documentation pack was also handed to the research student who entered the post-intervention data on the study database. In the absence of the research student, the packs were stored in a secured cabinet which was then accessed by the research student for review and data inputting on her return. The post-intervention data was matched with the baseline data for each participant by entering the participant's study number into the study database. To ensure that the data linking process was as accurate as possible, the research student verified that the study number recorded on the research study log corresponded to the study number documented on the baseline and post-intervention study documentation packs. The baseline and post-intervention documentation packs for each participant were then merged by the research student and stored together.

5.8.3 Data Management and Data Protection

Once data collection was completed, the full dataset for the study participants was extracted from the study database and held in a password-protected file on the Liverpool Heart and Chest Hospital server. The research student ensured that all data fields were complete. All patient identifiable data was removed or modified (e.g., age to replace date of birth) by the research student in order to pseudo-anonymise the data for the study, and to maintain patient confidentiality, prior to extraction from the NHS Trust server. The

pseudo anonymised data was then transferred via an encrypted pen drive to the research student's secure, password protected section of the University of Central Lancashire server as required. The extracted data was also shared with the supervisory team for the purpose of supporting data analysis using the University of Central Lancashire email system. Only aggregated data from the study is presented in the thesis or will be presented in publications and presentations generated from the findings of the study. The research study log was destroyed by the research student once data analysis was completed.

5.8.4 Quality Assurance

Staff Training

In service training about the study aims, objectives and protocol was scheduled in order to brief all members of staff about the prospective study. All members of the PR clinical team attended a series of hour long training sessions to familiarise themselves with the study protocol. There were several briefing sessions arranged for staff to review the protocol and ask the research student any questions they had or to clarify any issues. Assessing clinicians were required to be up to date with their clinical mandatory training, which includes identifying issues with capacity, in order to identify patients that may not be able to give informed consent. Copies of the study protocol were stored in each clinic file for clinicians to refer to it for guidance on how to conduct the different aspects of the study. All PR staff including the research student were trained in Good Clinical Practice including how to recruit study participants, with the support of the Research and Audit Department at the Liverpool Heart and Chest Hospital. In addition to training on the study protocol, all assessing clinicians also had their practice monitored by the research student using observed or joint clinic sessions.

Consent process

Pre-study information (Appendix 22) was sent out to potential participants with their PR appointment letter to explain that a study was being conducted within PR, the PR team were actively recruiting willing participants and that participation was on a purely voluntary basis. At the assessment appointment, patients who volunteered to participate in the study were given the opportunity to ask questions as part of the consent process, they were then required to sign a consent form if they still wished to participate in the study. A copy of the consent form plus another study information sheet (Appendix 22), study contact details and a study consent form (Appendix 23) were given to the study participant for their personal records.

Consistency

PR staff were given the opportunity for test runs of each aspect of the study protocol to familiarise themselves with the protocol and be aware of the importance of a consistent approach to all aspects of the study, starting from recruitment, consent, paperwork or questionnaire checks, study questionnaire storage and processing. To aid this process in clinic, study packs were packed and filed for each clinic site with the study paperwork arranged in a consistent format by the research student to ensure that all PR staff followed the same sequence as per the study protocol and to ensure a consistent approach across all the clinic sites involved in the study.

Rigour

All staff training was carried out by the research student to ensure that the information being disseminated to the PR clinical staff was accurate and consistent with the study protocol. The research student was also responsible for monitoring compliance with the study protocol through joint sessions and observed clinical sessions with the clinical staff involved in recruiting and collecting data for the study. Each study pack was compiled by the research student in preparation for clinic and reviewed at the end of each session by the research student to ensure that the consent and data collection processes had been adhered to and that documentation had been completed.

Data handling

In accordance with recommendations from the retrospective database study, a new PR outcomes database was constructed in conjunction with the Liverpool Heart and Chest NHS Hospital Informatics team to minimise the risk of human error and miscalculation of results. For example, set drop down menu options were built in for classification of disease severity, smoking status and respiratory disability status or entry cells were characterised as alphabetic or numeric with set points in order to minimise the risk of errors during data entry. All patient demographic information was verified and all questionnaires were checked by the assessing clinician as per routine practice to ensure that all the forms had been completed properly before the patient left the clinic. All data entered into the study database was also manually rechecked by the research student to ensure that all data fields were filled and the values entered were correct.

5.8.5 Data Cleaning

Once data collection was completed, the full dataset was extracted from the study database. Manual checks of the data were carried out by the research student who carried out frequency checks on each variable, checked the datasets for validation errors and conducted a final check against the study questionnaires. In total 32 errors were

detected out of 20017 data cells during this process, resulting in a percentage error of 0.2% for this stage. The errors were all transcription errors and were categorised as follows:

1. missing scores UCOPD questionnaire, Questions 14 – 18 (n=28)
2. missing total BCKQ score (n=2)
3. missing total UCOPD score (n=1)
4. missing total score CDSES (n=1).

Any identified errors were highlighted and the research student was responsible for identifying the study participant using the study key, locating the information from the hardcopy of the patient's clinical records and correcting the error or documenting the missing data.

Subsequent verification checks were carried out by two other members of the PR team to ensure that the data inputted and extracted matched the raw data. During this process, two errors both with the documentation of the 6MWT were detected, resulting in an error percentage of 0.001% for this stage. Any errors or missing data were highlighted and the research student was responsible for locating the hard copy of the original study questionnaires from the pre-assessment study packs or relevant clinical records and recording any missing data or correcting any errors in the recorded data. A final verification check of the extracted data by checking against the original study questionnaires and the patient records was carried out by the research student prior to data analysis being commenced to minimise the risk of recording errors within the dataset and maximise the accuracy of the study dataset. No errors were detected with the final verification check.

5.8.6 Statistical Methods

Descriptive statistics including mean [SD] or median [Interquartile range], histograms, minimum values and maximum values were computed for all participant characteristics. Estimation of mean levels and changes in levels of COPD self-management using the BCKQ, UCOPD and CDSES at baseline and post PR intervention was also carried out using point estimates, 95% confidence intervals were estimated and differences between groups or over time were explored using one sample or paired t-tests respectively. Differences in proportions were compared using Chi squared tests. Estimation of standardised differences was calculated using Cohen's D (Rosnow and Rosenthal, 1989) to estimate the size of the change. The relationships between the different self-management measures and their relationships with functional capacity, respiratory disability and emotional functioning were explored using scatterplots. The strength of any pairwise relationships was then assessed based on the scatterplot by computing a

Pearson Correlation Coefficient for interval data, Spearman's Correlation Coefficient for non-interval data and Kendall Tau-b for ordinal data. The strength of correlation (see Table 5.1) was determined using the guide on absolute value of correlation coefficients by Evans (1996).

Table 5.1 – Strength of Correlation (Evans, 1996)

r	Strength of Correlation
0.00 – 0.19	Very weak
0.20 – 0.39	Weak
0.40 – 0.59	Moderate
0.60 – 0.79	Strong
0.80 – 1.00	Very strong

In the analysis of the data from this study, correlations ≥ 0.40 were categorised as evidence of clinically important correlation with regards to strength of relationships. Commentary on observations were made on correlations <0.40 in terms of potential clinical implications, where considered appropriate. For all statistics, a P≤0.05 was considered statistically significant.

5.9 ETHICS AND GOVERNANCE CONSIDERATIONS

NHS ethics approval was granted on 01/06/15 (IRAS No: 163384) and ethics approval was granted on the 01/07/15 by the Science, Technology, Engineering, Medicine and Health (STEMH No 363) research ethics committee at the University of Central Lancashire (see Appendix 28). The main ethical considerations for this study included obtaining informed consent from participants; all staff involved in the recruitment of participants and data collection for the study completed Mental Capacity Act (MCA) training as part of the Mandatory training for the Trust ensure the prompt and accurate identification of patients unable to give informed consent and to ensure the privacy and dignity of vulnerable patients was maintained at all times. All staff involved in the study were required to complete Good Clinical Practice (GCP) training to ensure that good clinical practice was maintained throughout the study process. This was to ensure that the study protocol was adhered to and that robust research practices were implemented and upheld during all stages of the study. The second ethical consideration was regarding the protection of patient's personal information. Robust information governance strategies were utilised during the study to ensure the protection of patient information: All patient identifiable information was anonymised by the removal of any patient identifiers or transformation of data to ensure that patient confidentiality was maintained throughout, the study key was scheduled for destruction by the research student once data collection and anonymisation were completed. All data collected was scheduled for storage on the NHS Trust secure drive for 5 years after the completion of

the project as per Trust policies and University of Central Lancashire's Code of Conduct for Research and scheduled for destruction by the research student once the full retention period has expired. The third ethical consideration pertained to minimising the burden on the patient consenting to participate in the study. The potential risk and burden to patients was minimised by designing the study protocol to fit as closely as possible to routine clinical practice. The completion of the two study questionnaires only added a maximum of 5 - 10 minutes to the routine PR assessment time of 45 minutes, meaning that the burden on the study participants was relatively low. In terms of governance, the main consideration entailed ensuring that valid licenses or permissions were obtained for all measures to be used in the study: Approval to use the questionnaires was established by permission obtained for the use of the BCKQ and the UCOPD, statement of permission to use the CDSES for free and a license was purchased to enable the use of the HADS.

5.10 RESULTS

5.10.1 Baseline Participant Numbers

The number of COPD patients identified as being medically stable for PR was 270 but only 268 patients were considered to be eligible for the study during the nine months of recruitment from 01/08/15 to 30/04/16 as two patients were considered unable to consent. Out of those 268, 266 patients (99.3% of eligible patients) consented to participate in the study and commenced PR (See Figure 5.4 for Study Flowchart).

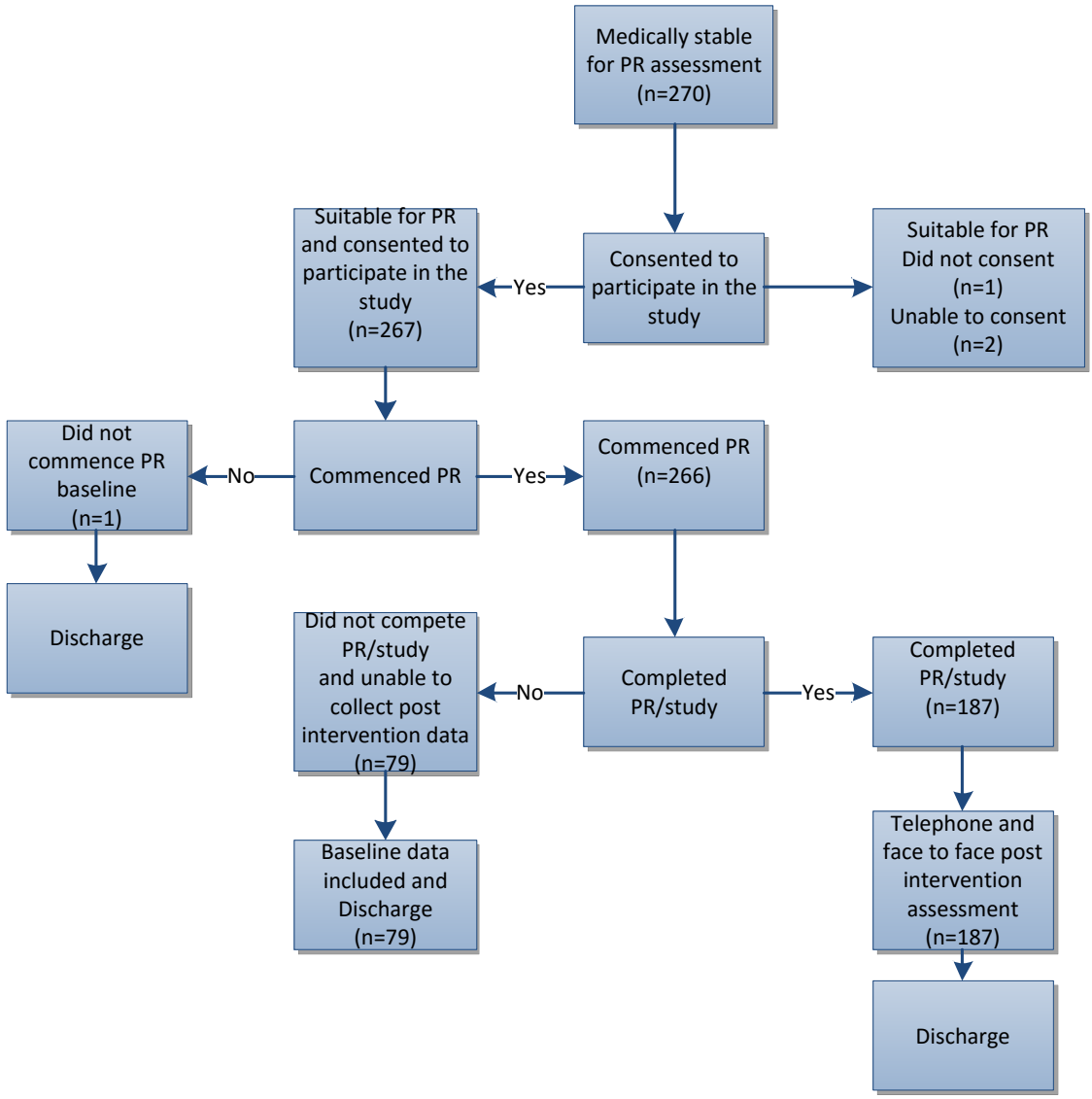

Figure 5.4 – Prospective Study Flowchart

5.10.2 Baseline Characteristics

Baseline characteristics of the 266 patients in the study cohort are described in three categories as follows:

- demographic information
- clinical characteristics
- self-management measures.

Demographic Information

The mean age of participants was 67 years old with 54.1% of the cohort being female and 40.6% being current smokers.

Table 5.2 – Baseline Demographic Information

Patient Demographics	Baseline Study Population (n=266)
Age (years):	
Mean	67
Median	69
SD	10.57
Range	28 - 93
Sex:	
Female	144 (54.1%)
Male	122 (45.9%)
Smoking Status:	
Current smoker	108 (40.6%)
Ex-smoker	145 (54.5%)
Non-smoker	7 (2.6%)
Never smoked	4 (1.5%)
Declined to declare	2 (0.8%)

Baseline Clinical Characteristics

Most patients had either moderate or severe COPD (72.2%), with the largest group being categorised with severe COPD (n=113, 42.5%). The largest group with regards to symptom severity was participants with an MRC Scale Score of 4 (n=97, 36.5%); overall, participants with symptomatic COPD (MRC score ≥ 3), made up 94.4% of the study cohort – see Table 5.3. The mean 6MWT was 190.3m, the study cohort had a mean HADS-Anxiety score of 8.8 and a HADS-Depression score of 8.0, both means were greater than the respective thresholds for mild anxiety and depression (Lee et al., 2013).

Table 5.3 – Baseline Clinical Characteristics

Patient Clinical Characteristics	Baseline Study Population (n=266)
FEV1 Rating:	
Normal spirometry	10 (3.8%)
Mild COPD	64 (24.1%)
Moderate COPD	79 (29.7%)
Severe COPD	113 (42.5%)
MRC* Dyspnoea Scale:	
1	1 (0.4%)
2	14 (5.3%)
3	91 (34.2%)
4	97 (36.5%)
5	63 (23.7%)
6MWT - Distance walked (m):**	
Mean	190.26
Median	210.00
SD	135.91
Range	0 – 500
HADS Anxiety (HADS A*):**	
Mean	8.80
Median	8.00
SD	4.96
Range	0 – 21
HADS Depression (HADS D**):**	
Mean	7.95
Median	7.00
SD	4.54
Range	0 – 21

*MRC – Min=1, Max=5, Direction of change – higher score denotes deterioration

*6MWT – Min=0, Max=1020, Direction of change – higher score denotes improvement

***HADS A – Min=0, Max=21, Direction of change - higher score denotes deterioration

****HADS D – Min=0, Max=21, Direction of change - higher score denotes deterioration

Baseline Self-Management Measures

The mean baseline self-management scores were 29.9 for the BCKQ, 48.8 for the UCOPD and 5.3 for the CDSES (table 5.4). The scores were normally distributed across the range of the scales (figure 5.5). However, the CDSES had a greater spread of participants across the scale with a high proportion of participants with scores ≤ 5 (52.3%) and with more participants at the extremes of the scale, i.e., 8.7% of participants with the highest scores (>=9) and 8.7% with the lowest scores (=<2). The mean values for the self-management measures at baseline were just less than the midpoint of the respective scales (see Table 5.4).

Table 5.4 – Baseline Self-Management Measures

Patient Self-Management Measures	Baseline Study Population (n=266)
BCKQ*:	
Mean	29.87
Median	30.00
SD	10.45
Range	0 – 58
UCOPD:**	
Mean	48.83
Median	52.80
SD	18.28
Range	0 – 99
CDSES*:**	
Mean	5.27
Median	5.27
SD	2.38
Range	1 – 10

* BCKQ – Min=0, Max=65, Direction of change - higher score denotes improvement

**UCOPD – Min=0, Max=100, Direction of change - higher score denotes improvement

***CDSES - Min=1, Max=10, Direction of change - higher score denotes improvement

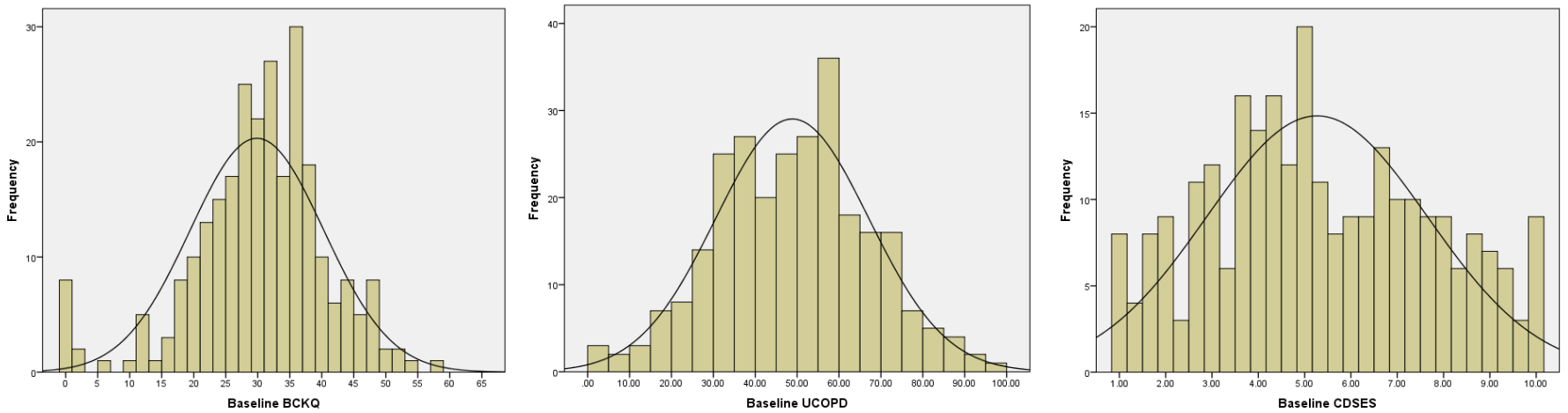

Figure 5.5 – Distribution of Baseline Self-Management Measures

5.10.3 Relationships at Baseline

Relationships between the Self-Management Measures

The results showed moderate positive correlation between baseline CDSES and baseline UCOPD (r=0.561, p<0.001) but no clinically important relationships between the BCKQ and the UCOPD (r=0.245, p<0.001) or CDSES (r=0.113, p=0.067).

Clinical Characteristics and Self-Management Measures

Analysis of the relationships between baseline clinical characteristics (MRC, FEV1, 6MWT, HADS-A and HADS - D) and the three self-management measures at baseline (BCKQ, UCOPD, CDSES) showed moderate negative correlation between baseline HADS-A and baseline CDSES (r=-0.476, p<0.001) and moderate negative correlation between baseline HADS-D and baseline CDSES (r=-0.565, p<0.001) but no other clinically important relationships between the clinical characteristics and the three self-management measures at baseline (see Table 5.5).

Table 5.5 – Relationships between Baseline Clinical Characteristics and Self-Management Measures

	Baseline BCKQ	Baseline UCOPD	Baseline CDSES
Baseline MRC			
Spearmans r	-0.112	-0.345	-0.143
p	0.067	<0.001	0.020
Baseline FEV1			
Spearmans r	-0.068	-0.057	-0.149
p	0266	0.356	0.015
Baseline 6MWT			
Pearsons r	0.138	0.153	0.294
p	0.025	0.012	<0.001
Baseline HADS-A			
Pearsons r	-0.027	-0.337	-0.476**
p	0.657	<0.001	<0.001
Baseline HADS-D			
Pearsons r	-0.090	-0.382	-0.565**
p	0.143	<0.001	<0.001

**** significant correlation**

5.10.4 PR Completion

Post Intervention Assessment

Of the 266 participants, a total of 187 (70.3%) participants completed the study and were able to provide complete datasets for analysis. Out of the 79 participants who did not complete the study, one (1.2%) transferred out of the area, five (6.3%) died, seven (8.9%) completed the programme but declined to provide follow up data for the study and 22 participants (27.9%) were unable to continue with the programme or the study due to significant deterioration in health. The remaining, 44 participants (55.7%) did not attend the programme and did not respond to correspondence and phone calls from the PR team to obtain follow up data.

5.10.5 Differences Between Groups

Differences Between Groups – Baseline demographic information

Comparisons of the baseline characteristics of those who completed the programme (completers) and those who did not complete the programme (non-completers) showed that non-completers were significantly younger than completers (mean age 64.5 years, SD 12.0) versus 68.6 years (SD 9.7, t=-2.9, df=264, p=0.003). There was no difference between groups in gender distribution (t=0.4, df=264, p=0.64) or smoking status (t=-234, df=264, p=0.82), although a larger proportion of smokers was observed in the non-completers group compared to the completers - see Table 5.6. Further analysis of the group that did not complete (n=79) showed that those who chose not to attend or lost contact with the PR team (n=51) were more likely to be still smoking (p=0.029) with significantly higher levels of HADS-D (p=0.038) and demonstrated lower BCKQ, UCOPD and CDSES scores compared to those who completed the programme (see Appendix 29).

Table 5.6 – Patient Demographic Information – Groups

	Completers (n=187)	Non-completers (n=79)	p value
Age:			
Mean	68.64	64.51	0.003
SD	9.71	11.95	
Range	33 - 93	28 - 84	
Sex:			
Female	103 (55.1%)	41 (51.9%)	0.64
Male	84 (44.9%)	38 (48.1%)	
Smoking status:			
Current smoker	72 (38.5%)	36 (45.6%)	0.82
Ex-smoker	106 (56.7%)	39 (49.4%)	
Non-smoker	5 (2.7%)	2 (2.5%)	
Never smoked	3 (1.6%)	1 (1.3%)	
Declined to declare	1 (0.5%)	1 (1.3%)	

Differences Between Groups – Clinical characteristics

Comparison of the baseline clinical characteristics of both groups showed worse levels of the HADS-A (t=2.5, df=264, p=0.013) and HADS-D (t=2.14, df=264, p=0.033) among those who did not complete compared to those who completed but no difference in disease severity, respiratory disability and distance walked with the 6MWT (see Table 5.7).

Table 5.7 – Baseline Clinical Characteristics - Groups

	Completers (n=187)	Non-completers (n=79)	p value
FEV1 Rating*:			
Normal spirometry	9 (4.8%)	1 (1.3%)	0.61
Mild COPD	45 (24.1%)	19 (24.1%)	
Moderate COPD	53 (28.3%)	26 (32.9%)	
Severe COPD	80 (42.8%)	33 (41.8%)	
MRC Dyspnoea Scale**			
1	1 (0.5%)	0 (0.0%)	
2	10 (5.3%)	4 (5.1%)	0.71
3	63 (33.7%)	28 (35.4%)	
4	66 (35.3%)	31 (39.2%)	
5	47 (25.1%)	16 (20.3%)	
6MWT* - Distance walked (m)**			
Mean	196.10	176.46	0.28
SD	135.78	136.05	
Min	0	0	
Max	500	500	
HADS – Anxiety (HADS A**)**			
Mean	8.32	9.96	0.013
SD	5.06	4.60	
Min	0	0	
Max	20	21	
HADS – Depression (HADS D***)**			
Mean	7.57	8.86	0.033
SD	4.52	4.50	
Min	0	0	
Max	21	19	

*FEV1 Rating – Forced Expiratory Volume in 1 second

**MRC – Min=1, Max=5, Direction of change – higher score denotes deterioration

***6MWT – Min=0, Max=1020, Direction of change – higher score denotes improvement

****HADS A – Min=0, Max=21, Direction of change - higher score denotes deterioration

*****HADS D – Min=0, Max=21, Direction of change - higher score denotes deterioration

Differences Between Groups – Baseline self-management measures

There was no difference in baseline BCKQ scores between completers and non-completers (t=-0.26, df=264, p=0.80), although non-completers demonstrated significantly lower levels of the UCOPD (t=-3.7, df=264, p<0.001) and observed lower CDSES (t=-1.9, df=264, p=0.059) compared to completers (see Table 5.8).

Table 5.8 – Baseline Self-Management Measures - Groups

	Completers (n=187)	Non-completers (n=79)	p value
BCKQ*			
Mean	29.98	29.62	0.80
SD	10.61	10.11	
Min	0	0	
Max	58	48	
UCOPD**			
Mean	51.47	42.58	<0.001
SD	18.39	16.51	
Min	0	8	
Max	99	74	
CDSES***			
Mean	5.45	4.85	0.059
SD	2.42	2.25	
Min	1	1	
Max	10	10	

* BCKQ – Min=0, Max=65, Direction of change - higher score denotes improvement

**UCOPD – Min=0, Max=100, Direction of change - higher score denotes improvement

***CDSES - Min=1, Max=10, Direction of change - higher score denotes improvement

5.10.5 Post Intervention Outcomes

Analysis of changes from baseline in self-management measures and clinical characteristics are described in the following section. As disease severity using the FEV1 is not routinely carried out as part of the PR programme's post intervention assessment, but as an annual follow-up with the patient's General Practitioner (GP) in Liverpool, this variable was excluded from the post-intervention data analysis.

Post Intervention Outcomes - Self-management measures

The self-management measures all demonstrated statistically significant improvements post PR intervention: The BCKQ score demonstrated an improvement of 27.7% which was statistically significant (t=-12.2, df=186, p<0.001, 95% CI 7.00 – 9.66). The histogram of change in BCKQ shows a fairly normal distribution across the range with a notable number of participants demonstrated no change in BCKQ score (see Figure 5.6).

The UCOPD score demonstrated a 23.29 point increase, an improvement of 45.2% which was statistically significant (t=-17.1, df=186, p<0.001, 95% CI 20.63 – 26.07). The histogram of baseline UCOPD is normally distributed but at post intervention demonstrates a significant shift to the right. The histogram of change in UCOPD shows normal distribution across the range of change available – see Figure 5.7. The CDSES score demonstrated a 1.66 point increase, an improvement of 30.9% which was statistically significant (t=-10.4, df=186, p<0.001, 95% CI 1.33 – 1.99). The histogram of baseline CDSES was normally distributed and at post-intervention, the histogram demonstrates a positively or right skewed distribution. The histogram of change in CDSES also showed fairly normal distribution across the range of change available with a spike demonstrating a high frequency of participants with no change in CDSES (see Figure 5.8).

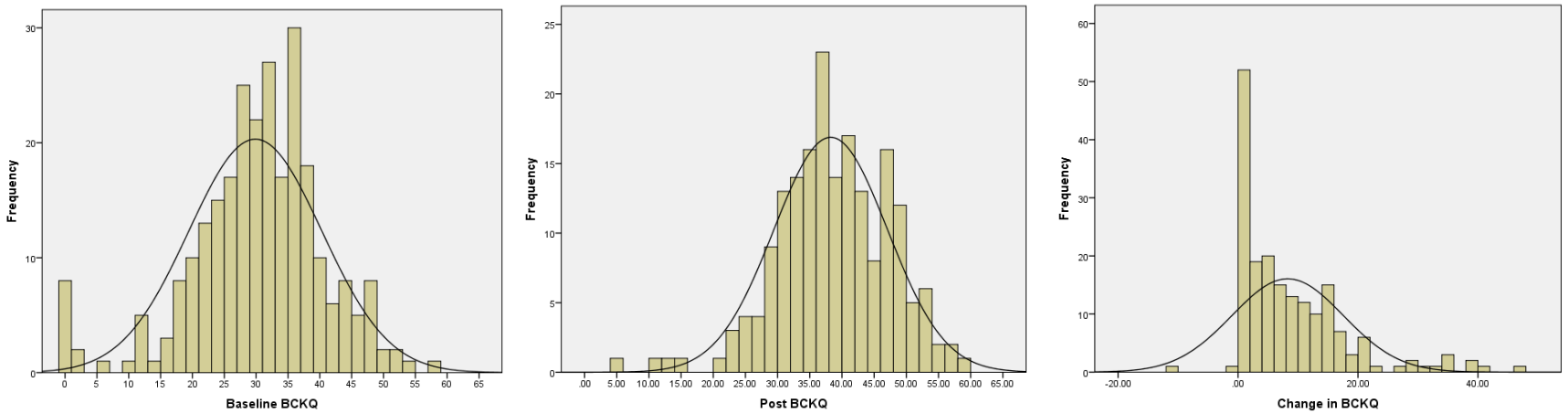

Figure 5.6 – Distribution of Self-Management Measure: BCKQ

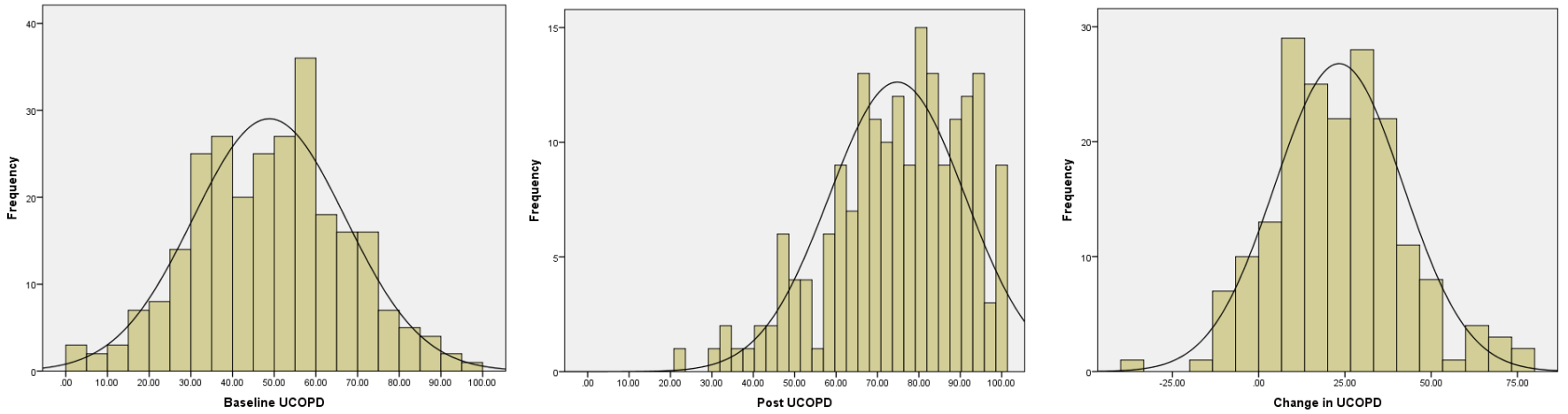

Figure 5.7 – Distribution of Self-Management Measure: UCOPD

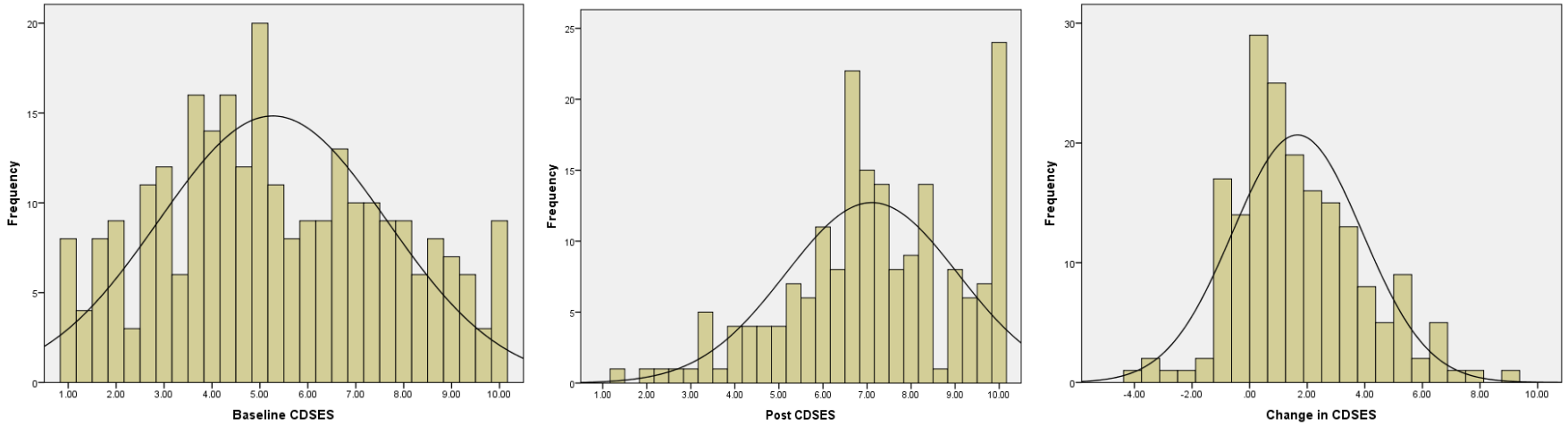

Figure 5.8 – Distribution of Self-Management Measure: CDSES

Analysis of the relationships between baseline and post-intervention self-management measures demonstrated weak - moderate positive correlation between the baseline values and post intervention values (see Table 5.9).

Table 5.9 – Self-Management Measures

(n=187)	Baseline	Post Intervention	Change (% change)	Standardised Difference	Paired t Test	df	p
BCKQ*:							
Mean	29.98	38.25	8.27 (27.7%)	0.89	-12.2	186	p<0.001
CI – lower Bound	28.34	36.97	6.93				
CI – Upper Bound	31.50	39.54	9.61				
SD	10.61	8.84	9.29				
Range	0 - 58	5 - 58	-11 - 47				
UCOPD:**							
Mean	51.47	74.76	23.29 (45.2%)	1.26	-17.1	186	p<0.001
CI – lower Bound	48.88	72.26	20.61				
CI – Upper Bound	54.34	77.26	25.97				
SD	18.39	16.42	18.56				
Range	0 - 99	22 - 100	-36 - 75				
CDSES*:**							
Mean	5.45	7.11	1.66 (30.9%)	0.73	-10.4	186	p<0.001
CI – lower Bound	5.09	6.82	1.33				
CI – Upper Bound	5.82	7.39	1.99				
SD	2.42	1.96	2.26				
Range	1 - 10	1 - 10	-4 - 9				

* BCKQ – Min=0, Max=65, Direction of change - higher score denotes improvement

**UCOPD – Min=0, Max=100, Direction of change - higher score denotes improvement

***CDSES - Min=1, Max=10, Direction of change - higher score denotes improvement

The BCKQ at the post intervention stage demonstrated a slight shift to the right in comparison to the baseline BCKQ data and was skewed with data distributed between 10 - 60 across an available range of 0 – 65 (see Figure 5.6). The post intervention UCOPD data demonstrated a significant shift to the right compared to the baseline UCOPD data and was skewed with the peak shifting to between 60 – 100. A notable decrease in the number of participants was observed at the lower end of the scale and an increase in the number of participants at the top end of the scale (see Figure 5.7). Post intervention CDSES also demonstrated a shift to the right compared to the baseline CDSES data and was skewed with the peak shifting to between 4 – 9. Notable change in the frequencies of participants at the lower and higher ends of the scale were also

observed in the post intervention dataset compared to baseline – see Figure 5.8. Using Cohen's guidelines for effect size – Table 5.10 (Rosnow and Rosenthal, 1989), the BCKQ and UCOPD demonstrated large sized change from baseline and the CDSES, medium sized change from baseline (see Table 5.9).

Table 5.10 – Cohen's d Size of Effect

Size of Effect	d	% variance
Small	0.2	1
Medium	0.5	6
Large	0.8	16

Post Intervention Relationships – Self-management measures

Analysis of the post intervention relationships between the self-management measures showed moderate positive correlation between baseline and post intervention values of the UCOPD (Pearsons r=0.436, p<0.001) and the CDSES (Pearsons r=0.487, p<0.001) respectively. The results also demonstrated a strong positive correlation between post UCOPD and post CDSES (Pearsons r=0.700, p<0.001) but there was a lack of any clinically important correlation between post BCKQ scores and the other two measures of self-management (post UCOPD Pearsons r=0.236, p<0.001 and post CDSES Pearsons r=0.128, p=0.081).

Analysis of the relationship between baseline self-management and change in self-management measures showed a strong negative correlation between baseline UCOPD and change in UCOPD (Pearsons r=-0.605, p<0.001) as well as between baseline CDSES and change in CDSES (Pearsons r=-0.653, p<0.001). There was no correlation between baseline BCKQ and change in BCKQ (Pearsons r=0.102, p=0.167), change in UCOPD (Pearsons r=-0.041, p=0.573) or change in CDSES (Pearsons r=0.013, p=0.860). Baseline UCOPD also did not correlate with change in BCKQ or change in CDSES (see Table 5.11).

Table 5.11 – Relationships between Baseline Self-Management Measures and Change in Self-Management Measures

	Change in BCKQ	Change in UCOPD	Change in CDSES
Baseline BCKQ			
Pearsons r	0.102	-0.041	0.013
p	0.167	0.573	0.860
Baseline UCOPD			
Pearsons r	-0.041	-0.324	-0.605**
p	0.581	<0.001	<0.001
Baseline CDSES			
Pearsons r	-0.089	-0.336	-0.653**
p	0.227	<0.001	<0.001

**** significant correlation**

Analysis of the relationships between post-intervention self-management measures showed moderate positive correlation between post UCOPD and change in UCOPD (Pearsons r=0.453, p<0.001). The results showed no clinically important correlation between post BCKQ and change in BCKQ (r=0.315, p<0.001), post BCKQ and change in UCOPD (r=0.004, p=0.962) or change in CDSES (r=0.043, p=0.558). There was also a lack of correlation between post CDSES and change in UCOPD (Pearsons r=0.246, p<0.001) or change in CDSES (Pearsons r=0.344, p<0.001).

Analysis of the changes in the self-management measures using Pearsons correlation showed a moderate positive correlation between change in UCOPD and change in CDSES (Pearsons r=0.575, p<0.001) but no correlation between changes in BCKQ and changes in UCOPD (Pearsons r=0.047, p=0.526) or changes in CDSES (Pearsons r=0.045, p=0.539).

Post Intervention Outcomes - Clinical characteristics

Cross tabulation of baseline and post intervention MRC scores for the study cohort showed that the distribution of MRC scores demonstrated a shift from higher levels of respiratory disability to lower levels of respiratory disability post intervention (see Table 5.12), however, this was not statistically significant (p=0.872).

Table 5.12 – Change from Baseline (Clinical Characteristics)

(n=187)	Baseline	Post Intervention	Chi squared	df	p
MRC* Dyspnoea Scale:					
1	1 (0.5%)	7 (3.7%)	9.89	16	0.872
2	10 (5.4%)	25 (13.4%)			
3	65 (34.8%)	64 (34.2%)			
4	67 (35.8%)	63 (33.7%)			
5	44 (23.5%)	28 (15.0%)			

*MRC – Min=1, Max=5, Direction of change – higher score denotes deterioration

All clinical outcomes demonstrated statistically significant improvement post PR intervention with the results showing a 28.0% improvement in the 6MWT (t=-8.7, df=186, p<0.001), 13.7% improvement in HADS Anxiety (t=5.5, df=186, p<0.001) and 15.4% improvement in the HADS Depression score (t=5.3, df=186, p<0.001). Using Cohen's guidelines for effect size (see Table 5.10), the SWT demonstrated medium sized change from baseline, anxiety and depression demonstrated small sized change from baseline - see Table 5.13.

Table 5.13 – Change from Baseline (Clinical Characteristics)

(n=187)	Baseline	Post Intervention	Change	Standardised Difference	Paired t Test	df	p
6MWT* – Distance walked (m):							
Mean	196.10	251.02	54.92 (28.0%)	0.63	- 8.7	186	<0.001
Median	210.00	280.00	20.00				
CI – lower Bound	178.29	232.84	42.42				
CI – Upper Bound	215.19	269.47	67.43				
SD	135.79	128.43	86.68				
Range	0 - 500	0 - 500	-410 - 380				
HADS – Anxiety:**							
Mean	8.32	7.27	1.05 (13.7%)	0.41	5.5	186	<0.001
CI – lower Bound	7.58	6.51	0.68				
CI – Upper Bound	9.04	8.02	1.42				
SD	5.06	5.04	2.59				
Range	0 - 20	0 - 20	-18 - 8				
HADS – Depression*:**	7.57	6.53	1.04 (15.4%)	0.39	5.3	186	<0.001
Mean	6.89	5.89	0.65				
CI – lower Bound	8.19	7.14	1.42				
CI – Upper Bound	4.51	4.21	2.66				
SD	0 - 21	0 - 17	-20 - 5				
Range							

*6MWT – Min=0, Max=1020, Direction of change – higher score denotes improvement

**HADS A – Min=0, Max=21, Direction of change - higher score denotes deterioration

***HADS D – Min=0, Max=21, Direction of change - higher score denotes deterioration

Post Intervention Relationships – Clinical characteristics

Analysis of the relationship between post intervention clinical outcomes and the self-management measures (see Table 5.14) showed a moderate negative correlation between post HADS-A and post UCOPD and post CDSES. HADS-D was also shown to have moderate negative correlation with post UCOPD and strong negative correlation with post CDSES. There were no clinically important relationships between post MRC or post 6MWT with the BCKQ, UCOPD or CDSES at either time interval (baseline or post intervention).

Table 5.14 – Relationships between Post Clinical Characteristics and Post Self-Management Measures

	Post BCKQ	Post UCOPD	Post CDSES
Post MRC			
Spearmans r	-0.208	-0.226	-0.387
p	0.004	0.001	<0.001
Post 6MWT			
Pearsons r	0.317	0.285	0.384
p	<0.001	<0.001	<0.001
Post HADS-A			
Pearsons r	-0.164	-0.406**	-0.516**
p	0.025	<0.001	<0.001
Post HADS-D			
Pearsons r	-0.181	-0.413**	-0.563**
p	0.018	<0.001	<0.001

**** Significant Correlation**

Analysis of the relationships between post intervention clinical outcomes (post MRC, post 6MWT, HADS-A and HADS-D) and change in the self-management measures using showed no correlation with changes in the self-management measures (BCKQ, changes in the UCOPD or changes in the CDSES).

5.10.7 Summary of Main Findings

The main findings of this study were that out of the 270 COPD patients eligible to participate in the study, 266 (98.5%) consented to participate in the study and started the programme. Of these, 187 (69.3%) participants completed the study and 79 participants did not complete. All clinical outcomes and self-management measures demonstrated positive change post PR intervention. Baseline characteristics of those who completed and those who did not complete showed that those who completed were older, had worse functional capacity, worse levels of anxiety and worse levels of depression. There results showed a lack of correlation between BCKQ and other self-management measures at baseline, post intervention and change from baseline. There was a positive correlation between UCOPD and CDSES at baseline, post intervention and change from baseline but a lack of a relationship between self-management measures and patient demographic or clinical characteristics. The only exception was the relationship between emotional functioning (depression) and CDSES at baseline and post intervention stages.

5.11 DISCUSSION

In the following sections, the main findings of the study, strengths of the study, weaknesses and implications of the study findings for clinicians and researchers will be discussed.

5.11.1 Study Cohort

Two hundred and sixty-six participants were recruited over the nine-month study recruitment period. The mean age of the study cohort was 67 years, there were more females than males and more current smokers than ex-smokers or non-smokers. Most COPD patients had an MRC score of 3 or above. The patient demographic and clinical characteristics of this study cohort were similar to patients routinely enrolled in the Liverpool PR service as compared to the retrospective analysis of collected data from the PR database. Although these characteristics are inconsistent with the findings of the most recent Cochrane review of PR intervention (McCarthy et al., 2015), these characteristics are consistent with characteristics that clinical guidelines such as NICE guidelines (2004 and 2010) suggest are the types of patients who are suitable for PR. According to NICE (2004, 2010), COPD is unusual in people under 40 years old, patients

with MRC score ≥3 are more likely to benefit from PR and patients with very severe COPD are less likely to benefit from PR.

5.11.2 Baseline Self-Management Scores (BCKQ, CDSES and UCOPD)

At baseline, mean self-management scores were low: the mean score for the BCKQ was 29.9 (SD 10.45), 48.8 (SD 18.28) for the UCOPD and 5.3 (SD 2.38) for the CDSES, suggesting that patients' pre-intervention self-management ability may be poor. The only baseline self-management measure in common with the retrospective study was the BCKQ and the baseline BCKQ from the retrospective study was similar to the value observed in this study with a mean score of 29.2 (SD 11.0). The baseline BCKQ levels from the prospective analysis of Liverpool PR health outcomes are consistent with results reported by five studies: Hill et al. (2010) reported baseline mean BCKQ score of 27.6 (SD 8.7), Ward et al. 2011 reported 28.3 (SD 10.30), Zhang et al., 2014 reported 30.4 (SD 9.6), Lo and Ong (2016) reported overall BCKQ baseline values <50% of the scale and Khan et al., 2017 reported 31.5 (SD 10.7). Two studies have reported baseline scores >50% of the scale; Wong and Yu (2016) reported baseline mean BCKQ of 40.1 (SD 10.6) and Chaplin et al., 2017 reported mean baseline BCKQ of 37.1 (SD 12.5) in their PR group. However, Wong and Yu (2016) had an intervention cohort that had previously had COPD education and the eligibility criteria for Chaplin et al. (2017) required participants to be web literate, both suggesting that previous self-management education may have contributed to the participants demonstrating higher baseline levels for the BCKQ compared to other studies and the values reported in this thesis.

The other two measures of self-management (UCOPD and CDSES) have less of a research base to rely on for comparison purposes. O'Neil et al. (2012) and Cosgrove et al. (2013) only report on change in UCOPD and did not present baseline or post intervention values for Section A of the UCOPD in their respective studies, therefore, the mean UCOPD score of 48.8 from the prospective study cannot be compared to other studies currently. The mean score of 5.3 for the CDSES in this prospective study was consistent with the mean CDSES of 5.9 for self-efficacy to manage disease in general (Kim et al., 2012) and a baseline mean of 4.9 reported by Ritter and Lorig (2014). The distribution of the CDSES scores was normal with 17.1% of participants having scores within the top 20% of the scale, suggesting potential ceiling effect with the scale (Marx et al., 2005; Terwee et al., 2007 and Wamper et al., 2010). This raises the possibility that there may be a subset of patients who already have good knowledge and self-management skills. These results suggest that the "one size fits all" approach to applying PR self-management education strategy may not be appropriate to all patients attending the programme and queries whether patients identified as being on the higher end of the

self-management scales require the same level of input or if their needs may be better managed by shorter PR courses or a modified bespoke approach to meet individual needs. The use of shorter interventions or less resource intense approach could reduce health care costs and enable resources to be targeted at those who require them. Although there is very little research currently to support this notion within PR for COPD patients, Wagg (2012) identified a similar concept with regard to the medical management of COPD; their theory is that self-management sits along a continuum of care and the level of clinical support provided should be decided based upon the individual's needs. Gallefoss (2004), Bourbeau and Nault (2007) and Janssen and Wouters (2013), also recommend pre-testing of patient traits might be valuable in the development of bespoke health interventions to meet patient needs. This suggests in the case of PR, baseline levels could be used as a predictive measure of the level of support the patient may require in terms of length of programme, intensity of programme, self-management education strategies applied and supportive or coping strategies put in place for the patient.

5.11.3 Post Intervention Levels of Self-Management

Three months after baseline assessment, patients' COPD knowledge (BCKQ), understanding (UCOPD) and self-efficacy (CDSES) improved in those who attended the Liverpool PR programme, suggesting that these measures of self-management were responsive to PR intervention. In line with what was expected from the systematic review of the literature reported in Chapter 4, overall mean scores improved for all self-management measures. There was a statistically significant relative increase in disease knowledge (BKCQ, 27.7%), patient understanding of the disease (UCOPD, 45.2%) and disease self-efficacy (CDSES, 30.9%). These findings are notably higher than the findings reported by other studies; White et al. (2006) reported an 11.9% change in BCKQ scores from baseline post PR intervention when they looked at assessing the results of COPD patient education; Hill et al. (2010) reported the BCKQ increased from 27.6 +/- 8.7 to 36.5 +/- 7.7 (15%) in BCKQ following disease specific education; Cosgrove et al. (2013) reported a change of 10.6% (95% CI 6.9 to 14.4) in BCKQ in UCOPD in the adaptation of the Living Well with COPD Programme which was imbedded into a PR programme. Differences in the characteristics of the study groups may have contributed to the difference in findings; White et al. (2006) had a cohort mean age of 70.9 years (SD 8.0) which was older than the mean age for the prospective study, predominantly more male (73.4%). In contrast in this study, the cohort was older (mean age 67 years, SD 10.6) and was 54.1% female.

As discussed above, as some of participants in the White study (White et al., 2006) had already received previous formal disease education, they may, therefore, have less

scope to improve substantially. Cosgrove et al. (2013) describe their cohort as having a mean age of 65 years (SD 9.0 years) and 52.1% male similar to this study but most were diagnosed with mild COPD and in contrast most of this study's participants were diagnosed with severe COPD. Furthermore, Cosgrove et al. (2013) adapted the Living Well with COPD programme which was delivered weekly on an individual basis in patients' homes with weekly telephone calls from a case manager. In contrast, the Liverpool PR self-management education component of the PR programme was delivered in primary or secondary care facilities with face-to-face support from health professionals as well as peer support from fellow patients: the importance of the role of healthcare professionals in the development of self-management skills (Grady, 2014) and peer support cannot be under estimated. Key themes that emerged from research into a self-management peer support programme by Lockhart et al. (2014), included the importance of specific-social support, sharing information and comparing self to others, suggesting that these useful interactions between similar groups of patients may serve to reinforce self-management strategies, behaviours and coping strategies, potentially accounting for the difference in measures of self-management observed in this prospective study. In addition, change in understanding of the disease with the UCOPD of 23.3 points (45.2%) was similar to the 26.8 point (41.2%) change in the UCOPD reported by Cosgrove et al. (2013). The 30.9% change in self-efficacy was also consistent with the change in CDSES of 36.0% reported in a similar self-management programme by Ritter and Lorig (2014). Even though there was an improvement in overall mean scores, there were still patients who had low post-intervention CDSES scores, 51.3% of had scores below the cohort median of 7.0. The reasons for this trend is unclear and supports the need for further research in order to develop better understanding of the concept of self-management and its constituents.

5.11.4 Relationships between Self-Management Measures

Analysis of the relationships between the different self-management measures indicated a lack of correlation between the disease knowledge (BCKQ) and disease understanding (UCOPD) or disease self-efficacy (CDSES) scores at baseline. Similar findings were found for these measures post intervention and when change scores were compared. The findings are consistent with those of Lee et al. (2014) who reported that levels of knowledge of disease did not show a significant relationship with levels of self-efficacy but they are inconsistent with the findings of O'Neil et al. (2012), who found a moderate positive correlation between the BCKQ and the UCOPD. This difference may be largely due to the differences observed in the respective COPD populations between a mixed COPD population as per this study and for example, a research study population, which

had been pre-screened for comorbidities, whose baseline and therefore, post intervention values may differ.

The lack of correlation between the BCKQ and the other measures of self-management study may suggest that knowledge in isolation may not be an adequate measure of self-management. Bearing in mind, the multi-factorial nature of self-management, this was an unexpected trend to emerge from this cohort. Wortz et al. (2012), included lack of knowledge, daily uncertainty relating to the disease and helplessness as some of the major factors that affect a patient's ability to live with COPD and the ability to self-manage their condition. Lack of disease knowledge would limit the scope of the patient's understanding of the disease, awareness of coping strategies to manage it and health behaviours that may stabilise or improve their chronic condition such as smoking cessation. One could, therefore, assume that there should be some relationship between disease knowledge, understanding and the translation of those two components into practical application and self-efficacy. However, the lack of correlation indicates that knowledge in this case may not necessarily translate automatically into better understanding or the practical application of the knowledge into managing the disease. Although no other study has investigated the relationships between these three measures of self-management for direct comparisons to be made, Bourbeau et al. (2004) and Wood-Baker et al. (2012) elude to knowledge alone being insufficient to effect behavioural change. These findings support the argument that self-management knowledge may not translate into self-efficacy, this means that improvements in disease knowledge does not necessarily mean that the patient's health behaviour or application of that knowledge into practical self-management of their condition will change. For example, patients may know that smoking causes health problems such as COPD and lung cancer, however, this knowledge may not necessarily translate into that patient stopping smoking. This suggests that a behavioural component is an essential part of the transition from acquiring increased knowledge about the condition and how to manage it and actually implementing or complying with self-management strategies geared towards managing the condition (Wood-Baker et al., 2012). Understanding the mechanism of how this would work in the COPD population and within the PR setting, would be the key to optimising benefits of the intervention for that patient group.

It could also be possible that the lack of correlation between the BCKQ and the other measures may indicate that the different measures of self-management are in essence measuring different constructs. This relationship between disease understanding and self-efficacy was observed for post intervention scores and for change in score between baseline and post intervention). This suggests that the UCOPD and CDSES tools may

be measuring similar or overlapping but not identical constructs. Both questionnaires cover symptom management and impact of symptoms. However, with the UCOPD, these are disease specific and address dyspnoea, exacerbation, respiratory medication, etc. Whereas, the CDSES is a generic measure of self-management, with generalised references to symptoms and impact of symptoms. The correlation between disease understanding (UCOPD) and self-efficacy (CDSES) demonstrated in this study is consistent with the supposition that increased understanding of disease, impact of disease, indications for behavioural change such as, compliance with medication, smoking cessation, diet, exercise and other lifestyle change factors, may strongly influence change in health behaviour and improve confidence to manage the condition (Arnold et al., 2006; Apps et al., 2013). It also supports the notion that improved knowledge does not necessarily translate into self-efficacy through the lack of a substantial relationship between the BCKQ and the other two measures of self-management. The lack of evidence regarding self-management in COPD also extends to the identification of appropriate measures for self-management as per the findings of Cochrane reviews into self-management for COPD (Effing et al., 2007; Effing et al., 2009; Zwerink et al., 2014). For example, White et al. (2006) highlighted the need for further studies and RCTs for the BCKQ and O'Neil et al. (2012) recommend further research to develop minimum clinically important values for the UCOPD. The identification of appropriate measures to evaluate the efficacy of self-management education strategies for COPD patients attending PR will enable clinicians to ensure that the needs of their patients could be met through targeted and bespoke programmes of care that also improve health outcomes.

5.11.5 Relationships between Changes in Self-Management Measures and Changes in Clinical Outcomes

All clinical outcomes measured (functional capacity - 6MWT, respiratory disability - MRC and emotional functioning - HADS-A and HADS-D) demonstrated improvement post PR intervention. The results indicate no relationship between baseline clinical characteristics such as respiratory disability, disease severity and functional capacity with any of the self-management measurement scores (i.e., disease knowledge, understanding or self-efficacy) at baseline. This observation also held true for comparisons post intervention and for changes in measurements between baseline and post intervention. Although this is consistent with the findings of the retrospective study, the lack of a relationship between functional capacity and measures of self-management is not consistent with the review of the theory of self-management or the clinical assumption that with PR intervention, patients who become better skilled at symptom management may be more aware of strategies such as pacing techniques or breathing

exercises to manage breathlessness during activities of daily living, including when walking, enabling them to walk greater distances (NICE, 2010). This study finding is also inconsistent with findings by Nguyen (2008) who found that a dyspnoea self-management education programme for COPD patients resulted in significant improvement in self-reported endurance exercise time. However, the strength of the relationship between the two was not made clear. Wigal et al. (1999), Wood-Baker et al. (2012) and Apps et al. (2013) also established an association between patient physical activity levels and levels of self-efficacy through improved knowledge, symptom monitoring, symptom management and appropriate action planning. Again, the strength of the relationships between these variables and the mechanism by which these changes occurred were not made clear. The lack of clarity regarding these relationships and the process by which self-management skills develops further highlights the need for further research and better understanding of self-management, especially in the context of PR. Evans and Morgan (2007) and Apps (2013) outline the aim of self-management education as part of PR as being to instil a sustained lifestyle change in this patient group by developing patients' coping skills to maintain as active a lifestyle as possible, promoting correct use of drugs and encouraging the early identification of increasing symptoms heralding an exacerbation. In view of this unexpected finding, it would be reasonable to query if the time intervals at which these measures were reassessed in this study play a role in the nature of the results of the study, i.e., would review of these measures a few weeks or months post intervention rather than immediately post intervention, have demonstrated the relationship between self-management and the ability to maintain better health outcomes.

There was moderate negative correlation between baseline emotional functioning and baseline self-efficacy (Anxiety – $r=-0.5$, $p<0.001$ and Depression – $r=-0.6$, $p<0.001$). The results suggest that poor emotional functioning is associated with lower levels of self-efficacy which in turn may have adverse effects on ability to self-manage COPD. However, the correlation with post intervention levels of self-efficacy and disease understanding indicate the sensitivity to PR intervention to effect change. These findings are consistent with Ritter and Lorig (2014) who reported a similar relationship between self-efficacy and depression ($r=-0.5$, $p<0.001$). Although research shows that self-efficacy and confidence can be affected negatively by emotional dysfunction and these links are well established within research (Sheridan et al., 2011). It is important to note that the strength of the correlation in this relationship suggests that the CDSES is in essence measuring self-efficacy and not emotional dysfunction, even though both factors have the potential to affect each other. Analysis of the relationships between the disease knowledge, self-efficacy, disease understanding and depression showed

moderate negative correlation between baseline depression and baseline self-efficacy: The implications for these findings may be relevant in the development of proactive and responsive PR programmes of care, i.e., the use of baseline measures of clinical outcomes, such as, emotional functioning and self-efficacy in advance of PR, establishing appropriate supportive and coping strategies for patients in order to optimise their potential to benefit from PR intervention.

5.11.6 Self-Management Scores of Non-Completers

Of the 266 participants who agreed to take part, 79 did not complete the PR programme. A number died but 73 declined or dropped out of the programme (non- attenders). This failure to complete (non-completers), was similar to that observed in the analysis of the routine database. The demographic characteristics of participants that completed or did not complete the study were similar except for age; the group that completed were older than those who did not and this is consistent with the findings of the retrospective study. Sirey et al. (2001) suggest that patient compliance is positively related to age. This is supported by the findings of a review by Krousel-Wood et al. (2004) who suggested that health-related compliance was positively related to age over 60 years old. Corlette (1996) specifies that that elderly patients with normal cognitive function are more compliant than their younger contemporaries. The rationale for this difference in behaviour may be that older patients with worse levels of disability, disease severity, more comorbidities and who may be more symptomatic, may be more likely to comply. NICE (2004, 2010) suggest symptomatic patients may benefit more from interventions, such as, PR using the same rationale. Other studies have observed that older patients may have different behaviour due to cultural or generational differences which mean that they are more likely to comply with medical intervention (Lacasse et al., 2005; Jin et al., 2008). On the other hand, apart from the correlation between advancing age and compliance, Fischer et al. (2009) identified inconvenient timing as a barrier to completion of PR, which means work commitments, family related responsibilities, such as, childcare commitments, and other responsibilities that younger patients may have could increase their risk of not completing PR. Keating et al. (2011) also reported logistical issues such as transport, access to public transport and parking as contributing to reasons why patients may not complete PR. Younger patients may also have greater levels of responsibilities and may struggle to coordinate the attendance of a PR programme in addition to work or family commitments such as child care responsibilities. These findings may have relevant implications to how PR services may be designed in the future to accommodate the different needs of the various patient groups attending the programme and, perhaps, enhance completion rates.

There were other differences observed between those who completed and those who did not complete the study with the results suggesting that those who did not complete had higher levels of anxiety (p=0.013) and depression (p=0.033) compared to those who did complete the programme. Non-completers also demonstrated significantly lower levels of disease understanding (p<0.001) compared to completers and lower but not statistically significant disease self-efficacy (p=0.059), but baseline levels of disease knowledge were similar in both groups (p=0.80). These findings suggest that poor emotional functioning, disease understanding and self-efficacy may be influencing factors in patients with COPD completing the programme and therefore, compliance with clinical regimen. These trends, albeit not statistically significant, were also seen when comparisons were made between completers and the non-completers subgroup, who did not attend rather than those who were unable to attend due to ill health or other reasons. In addition, this comparison showed that non-completers who did not attend were also more likely to be smokers: These findings are consistent with the findings of a systematic review of what prevents COPD patients from attending PR (Keating et al., 2011). This review reported that current smokers and those with depression were less likely to complete PR. Apps et al. (2013) found that the delivery of effective self-management skills requires the patient to have an acceptance of behaviour change, meaning that programmes need to be structured to develop knowledge and skills as well as to address attitudes to change so the patient can achieve the necessary behaviour change. For example, Lindqvist and Hallberg (2010) describe the stigma, sense of guilt due to self-inflicted disease, poor sense of self-worth and fear of prejudice that smokers experience. These observations may have clinical implications for practice to support those who do not attend and facilitate them being able to participate in PR by using pre-intervention measures of self-management to identify patients who may benefit from more support. The provision of pre-rehabilitative interventions to address issues such as emotional function may be a useful strategy to support behavioural change and facilitate the patient being able to engage effectively with PR self-management intervention, use healthcare resources more efficiently and reduce cost.

5.11.7 Strengths and Limitations

The strengths of the study included the prospective nature of the study which enabled the development of robust data collection and management protocols and allowed for the implementation of high quality assurance measures. Many of these were developed from the experience gained when undertaking the retrospective study, for example, minimising data errors. Also, following on from the retrospective study, the two (ISWT and 6MWT) measures of functional outcome were replaced by the 6MWT to facilitate comparison across the whole patient cohort. Through comparison with the retrospective

audit, it was also possible to show that the study cohort was similar to those attending the PR programme. The last observation is perhaps unsurprising as the study had a high response rate with 98.5% of eligible patients consenting to participate in the study and 70.3% of study participants completing the study.

The findings are also generalisable to a wider COPD population as the study population had patients with a range of disease severity and varying levels of respiratory disability, representative of patients with COPD (Trappenburg et al., 2011). This differs from those recruited to many RCT, when strict eligibility criteria are often applied (O'Shea et al, 2004). In addition, the study quality assurance processes led to a high attainment of data at both time intervals with no missing patient demographic, clinical or self-management measures data, serving to further strengthen the validity of the study findings (Sterne et al., 2009). The programme completion rates were similar to the retrospective study; an attempt was made to collect data from those who did not complete but patients who did not respond to correspondence or telephone contact were discharged and no further attempt to contact them was made after two attempts by the research student.

One criticism of the study may be that the assessment of self-management was carried out immediately post intervention, and there were no subsequent follow-up assessments. It may be that it takes some time to develop self-management skills and that this occurs outside the PR environment. All the studies in the literature review in the previous chapter included follow-up assessments outside the immediate post intervention assessment; follow-up in the studies were, three – five months in one study (7.7%), six months in one study (7.7%), 12 months in ten studies (76.9%) and 24 months in one study (7.7%). Sedano et al. (2009) suggested that the results of their study may have been limited by insufficient time frame to effect behavioural change post self-management intervention. Due to changes to the Liverpool PR service level agreement, there were no additional routine follow-up assessments after the post-intervention assessment. The decision was made to not add a follow-up for the study participants in order to minimise the burden on patients who had volunteered to participate in the study.

Another potential weakness was that the self-reported measures were completed while in the clinic and, although they were self-completed, there was a risk of participants providing responses that patients think the clinicians want to see or are more socially acceptable (Lavrakas, 2008). This might lead to higher scores post intervention. There is also the potential for recall bias, that is patients remembering what they said before (Coughlin, 1990). However, this was mitigated by the reassessment being carried out at

least 10 weeks after the baseline assessment so that participants were unlikely to remember their baseline responses and is unlikely, given the significant change in response scores between baseline and post-intervention.

The main weakness of this study was that the measures of outcome did not include some factors thought to be important indicators or measures of self-management as per the literature review in Chapter Four. These factors included, number of exacerbations (Sedano et al., 2009; Trappenburg et al., 2011; Fan et al., 2012), healthcare utilisation (Bourbeau et al., 2003 and 2006), exacerbation and symptom management such as rescue pack use, emergency GP appointments (Gallefoss and Bakke, 2000) and emergency department visits or admissions to hospital (Sedano et al., 2009; Wakabayashi et al., 2011; Fan et al., 2012; Siddique et al., 2012). These factors were not included in this study for two reasons. Firstly, the lack of access to accurate records regarding admissions or GP visits and secondly, the increased burden on the patient if they were required to provide additional information by filling out additional questionnaires as study participants.

5.11.8 Implications for Clinical Practice

Over the course of this programme of study, it is clear that there is a growing body of evidence on self-management. However, its incorporation in COPD interventions strategies such as PR still lacks a supporting body of evidence to form a consensus or to inform recommendations for clinical practice (Harris et al., 2008; Effing et al., 2009; Zwerink et al., 2014). Improving the insight, clinicians' knowledge base and the evidence base for self-management for COPD patients in PR could serve to contribute to the development of more effective PR services for COPD patients. As with other outcomes measures stipulated in the CSP's 2003 PR statement (CSP, 2003), it is good practice to establish a baseline and subsequently evaluate the effect of PR intervention on that measure. Clinicians need to consider what measures adequately measure self-management in their patient populations and enable them to evaluate the efficacy of their intervention as well as the effect of the intervention on health outcomes for patient. The observations of potential ceiling effects in the subset of patients with good self-management skills suggests that the "one size fits all" approach to PR and self-management education strategy in PR may not be appropriate for all patients attending the programme (Wagg, 2012). Clinically, this may result in services being able to provide higher standards of care by meeting patients' specific needs, better use of limited specialist resources and lower healthcare utilisation or costs. Further research into more bespoke programmes of care to inform the future design of PR programmes with regards to this aspect of care. In addition, observations of the difference between those who

completed and those who did not complete the programme indicate that emotional dysfunction (anxiety or depression), poor disease understanding and poor self-efficacy may contribute to an individual's ability to complete PR. It would therefore be reasonable to propose that pre-rehab intervention to address these issues may increase the probability of patients identified with anxiety, depression, poor disease understanding or poor self-efficacy completing the programme (Gallefoss, 2004; Bourbeau and Nault, 2007; Janssen and Wouters, 2013). This will enable clinicians to develop interventions that are designed to support the patient adequately enough to enable them to engage with the rehabilitative process. Further research to establish the feasibility of this and exploring the impact on completion rates as well as compliance with clinical regimen would be required. Better understanding of the COPD PR cohort and characteristics of those who not attend the programme is essential for clinicians to develop strategies or alternative approaches to support patients such as smokers and younger COPD patients to engage with the rehabilitative process and to develop self-management skills. Overall this research process has highlighted the importance for clinicians who routinely collect clinical patient data to utilise this data to understand the characteristics of their patient cohort in order to establish effective strategies to optimise their care, estimate an intervention effect for the care provided and establish an evidence base for practice. Being able to use this data to predict change or variations in the patient population may enable clinicians to be more proactive, responsive to patients' needs and be more proficient at delivery anticipatory healthcare rather than reactive healthcare.

5.11.9 Implications for Research

In view of the lack of correlation with the BCKQ and the correlation between the UCOPD and the CDSES, further research on measures of self-management with clinical measures or indicators of self-management such as exacerbation rates, admission frequency, hospital length of stay may be required to better understand the concept of measuring self-management in this patient population. According to Earley et al. (2011), mechanisms and materials to support the education component of PR are not widely available, this includes evidence on outcome measures, constituents of self-management programmes (Harris et al., 2008; Effing et al., 2007; Effing et al., 2009; Zwerink et al., 2014).

It is apparent by the lack of correlation between the self-management measures and the clinical outcomes in this study that the mechanism by which these changes occur is yet to be fully understood and further research to explore the concept of self-management in the management of COPD and PR is required (Zwerink et al., 2014), including its use in PR (McCarthy et al., 2015). This includes research to establish Minimal Clinically

Important (MCI) scores for self-management measures (White et al., 2006; O'Neil et al., 2012). This would contribute further to the design of future studies of PR intervention strategies and enable a better understanding of the clinical implications of research findings. The potential for a floor and ceiling effect with the self-management measures as seen with the CDSES as well as the characteristics of those who fail to complete PR, may also necessitate further research into the design and application of future PR strategies applied for COPD patients at the lowest and highest functioning ends of the self-management scales; these findings indicate that they may require alternate support and management strategies for them to be able to get the most out of attending PR (Apps et al., 2013).

5.12 CONCLUSION

In this chapter, a prospective study of the effect of the Liverpool PR self-management education strategy on health outcomes for COPD patients demonstrated significant improvement in functional capacity, respiratory disability, emotional function and three measures of self-management. The findings of this study suggest that, COPD patients attending the Liverpool PR programme had low levels of self-management prior to attending the programme but that following a combined self-management education an exercise rehabilitation programme COPD knowledge, disease understanding and disease self-efficacy post PR intervention improved as did respiratory disability, functional capacity and emotional functioning. There was a relationship between disease understanding and self-efficacy but no relationship between disease knowledge and understanding or self-efficacy. In regard to other outcomes, there was only a relationship between self-efficacy (CDSES) and depression (HADS-D). In the next chapter, a synthesis of the findings from all the three studies is presented along with further discussion on the implications for research and implications for clinical practice will be discussed.

CHAPTER SIX
THESIS CONCLUSION

6.1 INTRODUCTION

In the previous chapter, prospective analysis of PR data on self-management, functional capacity, respiratory disability and emotional functioning was discussed with the relationships between self-management and clinical outcomes being explored. In this chapter, an overview of the findings of the three studies and literature review carried out as part of this programme of study will be provided. The implications for PR clinical practice, research and the impact on the Liverpool PR service will also be outlined.

6.2 REFLECTION ON THE RESEARCH JOURNEY

The programme of studies has been challenging as the journey that I have taken has been quite different from the one that I had anticipated. Instead of establishing the efficacy of the Liverpool PR self-management strategy as the primary focus of this thesis, I think that my journey has been a very explorative one which has perhaps raised more questions than it answered. The clinician in me has sometimes found this challenging to come to terms with, however, the novice researcher developing in me has found this process an immensely useful in terms of foundation training in research skills. The attainment of these skills has given me the confidence to explore outside my usual boundaries and a safe environment to think outside the box of usual clinical convention or limitations. The development of this thesis has not only improved my knowledge and insight into the concept of self-management, its relevance in COPD and the potential benefits it has to offer in PR, it has also stirred my interest in further research. As a clinician, observing the impact on the Liverpool PR service and the change in practice resulting from this process has been inspirational, not just for me but for my colleagues. I feel that the best outcome of this explorative programme of study would be to be able to change how the design of PR services are considered in the future, contribute to the available evidence on the incorporation of self-management into routine PR practice, to improve the insight of fellow clinicians into self-management in PR and to inspire similar interest through sharing best practice among other colleagues outside my immediate professional circle.

6.3 SUMMARY OF MAIN FINDINGS

This thesis set out to explore the impact of self-management education incorporated into PR on clinical outcomes for patients with COPD, using the Liverpool PR strategy as an example. Due to the lack of a standardised PR format in the UK, it was important to establish the similarity of the Liverpool PR strategy to other PR programmes and to

establish the generalisability of any findings to the wider COPD population before exploring the impact of the strategy. Therefore, a survey of PR services in the North West of England was undertaken which showed that the Liverpool PR self-management education strategy was typical of the approach used across the region, although there were variations in the implementation of this strategy. There is still a lack of evidence on self-management incorporated into PR. After establishing that, retrospective analysis of the PR service outcomes database showed that PR intervention can improve functional capacity, self-management knowledge and emotional functioning in patients with COPD but showed no correlation between self-management knowledge and other health outcomes. The sustainability of these improvements over time varied, with functional capacity and emotional functioning (depression) being sustained and emotional functioning (anxiety) continuing to improve in the short term. Improvement in self-management knowledge was not fully sustained in the short term. The findings also indicated that participants' baseline self-management knowledge may influence completion of the programme and attendance at the follow up assessment. This infers that patients with a poor self-management knowledge of their condition may be more likely to have limited insight into their condition or its management and are therefore less likely to comply with a non-acute management strategy such as pulmonary rehabilitation.

The weak correlation between the changes in overall BCKQ score, changes in functional capacity and changes in emotional functioning justified the need for a systematic search of the available literature for self-management evaluation strategies for COPD to identify an appropriate measure of self-management and to inform the design of a prospective study to explore the trends in self-management measures and their relationship with clinical outcomes pre and post PR intervention. The prospective study demonstrated that measures of self-management and clinical outcomes improved with the Liverpool PR intervention but there was a lack of correlation between COPD knowledge and disease understanding and self-efficacy. There was also a lack of correlation between demographic and clinical characteristics with self-management measures, except for emotional functioning and CDSES at baseline and post intervention. This study served to identify important characteristics of the study population with regard to those who failed to complete the programme being younger with worse functional capacity, worse levels of anxiety and worse levels of depression.

The UK MRC Framework for complex interventions to improve health (see Figure 1.2, Page 42) has criteria to guide the development and evaluation of health behaviour change programmes (Troughton et al., 2015). The most recent MRC guidance suggests including development, feasibility, piloting, evaluation and implementation (Craig et al.,

2008; Moore et al., 2015). This framework suggests that an early task is the development of a theoretical understanding of the likely process of change with the planned intervention by drawing on existing evidence and theory (Troughton et al., 2015). In the next section (6.4), I will explain how the findings of from my studies contribute to the further development and evaluation of PR. The findings from the survey, retrospective study, literature review and the prospective study will contribute to better understanding of the theory and practice of self-management incorporated into PR in the context of the available evidence, including what constitutes self-management, what tools are used to measure self-management and the relationship between self-management and health outcomes.

6.4 SELF MANAGEMENT

6.4.1 Defining Self-Management and its Components

Collaboration between the patient and healthcare providers to promote self-management and optimal health outcomes in COPD is a splendid concept (Nici et al., 2014), but defining what this should look like, how it might work in practice and what components to include is challenging. The importance and relevance of self-management is reflected in how the structure of health systems cause patients to behave, i.e., people with long term conditions like COPD typically, spend only a few hours each year in contact with health services, for the rest of the time, they are 'self-managing' their condition (Lhussier et al., 2013). However, despite information and guidelines on self-management such as GOLD (2016), individuals with COPD seldom comply with the recommended self-care behaviours (Clari et al., 2017) and that little is known about what these individuals truly do to take care of themselves in their daily lives (Lomundal and Steinbekk, 2002; Monninkhof et al., 2004). Clinical trials testing self-management in COPD have had inconsistent results and although the evidence favours self-management interventions, there seems to be a large heterogeneity in the different effects of these interventions (Jonkman et al., 2016). Understanding the concept of COPD self-management as part of this exploratory process is a vital part of developing insight into its clinical relevance and informing the design of future innovative approaches to self-management education strategies in PR.

The results of the literature review in Chapter Four indicate that COPD self-management refers to engaging in activities that promote adequate medication technique, building physiological reserves, preventing adverse health outcomes, monitoring respiratory and emotional status, making appropriate disease management decisions and managing the effects of illness with prescribed or learnt coping skills. This is consistent with previous research such as Barlow et al. (2002) and Andenaes et al. (2014) which define self-

management as the individual's ability to manage symptoms, treatment, physical and psychosocial consequences and lifestyle changes when living with a chronic condition. These findings are consistent with more recent research by Clari et al. (2017) whose meta-synthesis of self-management research in people with COPD identified a set of self-management categories which included:

- prevention, control and management of the effects of COPD on respiratory symptoms
- prevention and management of limitations in daily activities, sleep problems, emotional discomfort, social life modifications
- acquisition of knowledge and skills for self-care

The results from this programme of study (retrospective study in Chapter Three and the prospective study in Chapter Five) indicate that post Liverpool PR intervention, dyspnoea-related limitation to activity was reduced, emotional functioning was improved, and disease knowledge and self-efficacy was also improved. The results also indicate that these improvements were maintained in the short term but further research is required to ascertain whether they are sustained over time.

In reviewing the relevance of COPD self-management to the COPD population and with regard to overall management of the condition, Kessler et al. (2006) identified that patients' COPD self-management knowledge was limited. Following on from that, Hernandez et al. (2009) and Clark et al. (2009) suggest that this lack of awareness might be related to the general absence of information available for COPD patients on the social and behavioural dimensions of self-management. Kaptein and Creer (2002) explored the concept of respiratory disorders and behavioural medicine in an attempt to expand the treatment paradigm for respiratory disease in order to address behavioural approaches to disease management in conjunction with traditional management approaches such as pharmacotherapeutic strategies. Although their research was successful in demonstrating how a self-management model can be used for respiratory disease management, unfortunately, it also demonstrated that there is still a lack of a consensus regarding skill development, self-efficacy and behavioural change. The lack of consensus is reflected in the findings of the survey of PR services in North West of England, which suggest there is no standardised approach to how self-management has been incorporated into traditional PR services or how self-management is evaluated in these services. This lack of consensus is also reflected in the lack of emphasis or emphatic detail placed on these components in the most recent clinical guidance for managing COPD such as the BTS Guideline on Pulmonary Rehabilitation in Adults (Bolton et al., 2013) and the most recent NICE quality standards (NICE, 2016). Kennedy et al. (2014) and Clari et al. (2017) found a lack of specific detail about patient self-

management behaviours and lack of detail of how health professionals could change people's behaviour in everyday practice. This lack of detail was integral to the failure of an evidence-based self-management support strategy for patients in primary care (Kennedy et al., 2014).

6.4.2 Self-Management Approaches

Some research suggests that self-management requires a multi-faceted approach such as is provided by the Liverpool PR self-management education strategy. It is thought that this multi-faceted approach is the method by which behavioural change can occur in COPD patients by enhancing their self-efficacy (Bourbeau et al. 2004, Effing et al., 2012 and Wood-Baker et al., 2012). The goal of self-management education is increased adherence to treatment as well as improving clinical outcomes (Bourbeau et al., 2004; Koff et al., 2009). Central to the concept of self-management is the promotion of self-efficacy, which refers to the individual's confidence in completing the behaviour required to reach a particular goal (Bodenheimer et al., 2002b).

The success of a self-management programme should correspond to the goals of self-management, i.e., acquiring key self-management skills and self-health behaviours (Bourbeau et al., 2004) but the ultimate goal of a self-management programme is to facilitate self-management practices necessary for optimal control of the disease (Monninkhof et al., 2003b; Blackstock and Webster, 2007; Tan et al., 2012; Wong and Yu, 2016). According to the British Columbia Ministry of Health's Self-Management Support strategy (2011), in the implementation of self-management as a healthcare intervention for patients with chronic conditions, health professionals can use a variety of techniques, singly or in combination. Techniques such as goal setting, checking the patient's readiness for self-management, developing manageable action plans, getting personalised feedback, self-monitoring, enlisting social support, checking patient commitment to key tasks and importantly, following up on patient goal achievement. In providing a system-wide strategy to guide clinicians in the management of chronic conditions, this Ministry of Health was able to implement self-management as a priority in clinical practice for all clinicians, regardless of the setting, to follow an intervention framework to support patients to develop self-management skills to manage their condition. There is currently no such intervention framework for self-management in COPD in the UK, resulting in a variety of management approaches that are inconsistently applied across different sectors of health care, depending on the priorities for the local health authority or clinical commissioning body.

When considering the development of a complex intervention such as the Liverpool PR programme, the MRC framework for complex interventions (Craig et al., 2008) proposes three components to the development:

1. identifying the evidence base
2. identifying/developing theory
3. modelling process and outcomes.

This programme of study, through its findings may serve to contribute towards the evidence-base on self-management education incorporated into traditional PR. In particular, the survey findings provide an overview of how many PR services exist within the North West of England, the PR service formats, service delivery, what components of self-management education are used and how self-management is assessed. The findings regarding the relationships between the three measures of self-management in the prospective study and information regarding the characteristics of COPD patients who complete the programme and those who do not may contribute towards identifying and developing theories on the incorporation of self-management education into traditional PR intervention for COPD patients.

6.4.3 Self-Management and Relationships

The multi-factorial nature of COPD and the complexities in its disease self-management is indicated through the trends and relationships observed in the findings from this study cohort, especially in view of the lack of correlation between the measures of self-management used and the clinical outcomes. When considered in the context of the theoretical concept of self-management, this may be further indication that factors such as knowledge, self-efficacy and behavioural change should be developed together in a collaborative effort to impact on self-management. The lack of a strong correlation between knowledge, understanding and self-efficacy demonstrated by the findings if this programme of study suggests that perhaps knowledge does not necessarily translate into behavioural change. Clari et al. (2017) found that despite the information available on the disease, individuals with COPD seldom comply with recommended self-care behaviours. This is substantiated by previous research which has shown that most studies into stand-alone COPD education included in a Cochrane review of self-management for COPD demonstrated no benefits (Harris et al., 2008). However, Bourbeau et al. (2004) found that acquired knowledge and self-management skills will result in enhanced self-efficacy and improved health behaviour. The results of this programme of study suggest a relationship between self-efficacy and emotional functioning. This is consistent with other research that indicates that higher levels of COPD-specific self-efficacy is associated with less anxiety and depression (Bentsen et al., 2013). The identification of these findings is consistent with the

identifying/developing theory component of the development phase in the MRC Framework for complex interventions (Craig et al., 2008).

Identifying and developing theory is an important part of the development phase of the MRC Framework but prior to that is identifying the evidence base (Craig et al., 2008). Part of this process is understanding how the current evidence links the intervention to practice processes, outcomes and their assessment. It is vital that those detailing or implementing interventions define precisely what the intervention entails (Moore et al., 2015). However, mechanisms and materials to support the delivery of the education component of PR are not widely available (Earley et al., 2011; Khan et al., 2017). A report from an expert panel concluded that publications on COPD self-management interventions lack detailed description of intervention content and process (Effing et al., 2012; Benzo et al., 2013). No “gold standard” on specific educational topics, which should be integrated in the educational programmes offered to COPD patients, is established (Stoilkova et al., 2013), further compounding the issue. This, in addition to the lack of emphasis and clinical guidance on self-management education for COPD in the most recent clinical guideline serves to highlight that currently, this component of COPD management incorporated into PR is still not at the forefront of the structured management of COPD. This is despite a growing body of evidence to support its use and usefulness in clinical practice: NICE (2017), the BTS guideline on PR in adults (Bolton et al., 2013) and the three most recent joint European Respiratory Society and American Thoracic Society clinical guidelines (Quaseem et al., 2011, Papi, Rabe and Rigau et al., 2017 and Wedzicha, Calvery and Albert et al., 2017), all include the use of self-management in their recommendations for practice. However, there is a lack of detail about the self-management component of COPD management in comparison to the detail provided in their recommendations for pharmacotherapeutic interventions. This need to provide detailed guidance for practice is supported by a growing body of evidence for the expansion of the treatment paradigm for respiratory disorders to be expanded to include behavioural medicine in conjunction with traditional methods such as pharmacotherapeutic strategies (Kaptein and Creer, 2002; Kennedy et al., 2014; Young et al., 2015; Wedzicha et al., 2017). This change is needed to address deficits identified in the disease management strategies for conditions like COPD (Kaptein and Creer, 2002; Kennedy et al., 2014; Young et al., 2015; Wedzicha et al., 2017).

6.4.4 Assessing or Measuring Self-Management

The findings from this programme of study suggest that components of self-management including disease knowledge, understanding and self-efficacy are responsive to self-management education incorporated into a traditional PR service. However, the lack of

a strong correlation between knowledge, understanding and self-efficacy, however, suggest that knowledge does not necessarily translate into behavioural change in patients and lends support to the argument that self-management in COPD should be assessed with a range of measures in conjunction with clinical and behavioural observations. In view of these findings, it may be reasonable to consider that, in a complicated condition such as COPD, self-management as a concept is too complex and multi-factorial to be measured by a single tool, such as any one of the self-management measures used in this study. This multi-dimensional assessment strategy may serve to provide a more comprehensive picture of an individual's self-management ability. However, further research is required to further explore this aspect of PR intervention, including the identification of appropriate outcome measures for self-management and appropriate time points to measure these outcomes. It will also be important to investigate the causal impact of these self-management measures on key health outcomes, such as functional and emotional functioning in order to gain further understanding and evidence related to the theory as to how self-management may work.

6.4.5 Developing Self-Management Skills

The findings of this programme of study demonstrate that self-management measures (disease knowledge, understanding and self-efficacy) and clinical outcomes such as functional capacity, respiratory disability, anxiety and depression improve following completion of the Liverpool PR programme. However it is apparent by the lack of correlation between the measures of self-management and the clinical outcomes that the mechanism by which these changes occur is yet to be fully understood in clinical practice. This is consistent with findings by Zwerink et al. (2014) and McCarthy et al. (2015) who then concluded that further research is required to explore this further.

The principles of self-management are developed in a number of theoretical models, of these, the self-efficacy theory is most widely referenced (Bandura, 1997). When applied to health, the self-efficacy theory suggests that patients are empowered and motivated to manage their health problems when they feel confident in their ability to achieve this goal, i.e., self-manage their condition. Key self-management skills include resource utilisation, patient-provider relationships, problem solving, decision making, early symptom recognition and taking action based on a predefined action plan (Bourbeau and Palen, 2009). As self-management health behaviours are performed with success in various situations of everyday life, patients develop an improved sense of self-efficacy. Self-efficacy is an important construct in self-management (Nici et al., 2006 and Andenaes et al., 2014) and refers to the confidence people have in their ability to perform actions that are required to deal with particular situations (Bandura, 1997). Many people

with COPD have high levels of dyspnoea that affects their functional performance and they have little or no confidence in their ability to manage or control the effects of dyspnoea, thus they have overall low self-efficacy (Siela and Zimmerman, 2003). Many COPD patients also seem to lose their sense of control over the disease and their lives, especially during an exacerbation or flare up of their COPD, which may lead to lower self-efficacy (Bourbeau et al., 2004 and Kara and Asti, 2004). Previous COPD research has found that a higher level of COPD-specific self-efficacy is associated with less anxiety and depression (Bentsen et al., 2013) and better mental health (Arnold et al., 20006). This is consistent with the findings of the prospective study which showed correlation between disease understanding and self-efficacy as well as correlation between self-efficacy and emotional functioning.

The increasing body of evidence suggesting self-efficacy is the key to attaining effective self-management; Bourbeau et al. (2004) and Wood-Baker et al. (2012) suggest that self-management requires a multifaceted approach to change behaviour in patients by augmenting self-efficacy. Wagg (2012) identified self-efficacy as an important aspect of behaviour change and by identifying deficits in self-efficacy and manipulating it, behaviour change might be more successful. Bischoff et al. (2012) states that comprehensive self-management programmes are based on the presumption that effective modification of behaviour can be attained only if patients' self-efficacy has been improved and that patients who have enough confidence in their ability to successfully respond to certain events, can more easily modify and maintain the desired behaviour. According to Bourbeau et al. (2008), it is this behavioural modification that should ultimately result in improved clinical outcomes, indicating that timing is important in the development of self-management skills and efficacy. Therefore, the method of assessing self-efficacy or the self-management measure used in the assessment and the timing of this assessment are key factors in accurately predicting the individual's self-management ability. This corresponds with the findings of both the retrospective database study and the prospective study which highlighted the outcome measures being used may potentially be inappropriate for measuring self-management. The lack of strong correlation immediately post intervention suggests that time to consolidate the self-management skills learnt, develop self-efficacy and effect behavioural change may not have been sufficient immediately post PR intervention.

6.5 PARTICIPANT CHARACTERISTICS

The other important finding of this programme of study was with regard to the characteristics of the study group. Both the retrospective and prospective studies identified younger patients who were still smoking, who had lower levels of disease

knowledge, understanding and self-efficacy and higher levels of anxiety and depression as being more likely not to complete the programme. The retrospective study also highlighted those who were poorer with lower socioeconomic scores as being more likely to not complete the programme. According to Apps (2013), delivery of effective self-management requires the patient to have an acceptance of behavioural change. This means that self-management programmes need to be structured to develop knowledge and skills as well as address attitudes to change, so the patient can achieve the necessary behaviour change. Understanding the behavioural and practical challenges within this patient cohort will serve to inform the design of strategies to identify these patients early enough for effective intervention, develop effective self-management strategies to facilitate engagement or compliance with clinical intervention and to develop effective coping strategies to aid the attainment of self-management skills.

This aspect of work is very important as research recognises that there are behavioural and compliance challenges in the management of this patient group. The compliance rate of long-term therapy on average is 50% for patients with COPD in developed countries such as the UK (Blaise et al., 2004) and is as low as 32% with regard to PR (Zhong et al., 2008). Self-management strategies are complex and require significant effort and commitment from patients, including, smoking cessation, breathing control techniques, coughing or chest clearance techniques, commitment to exercise, regular inhaled medication, self-initiation of corticosteroids or antibiotics at the onset of an exacerbation, deploying effective behavioural skills and self-management education (Ries et al., 2003). Understanding and measuring patients' health literacy in relation to behavioural risk factors is an important goal in the prevention and detection of chronic disease (Taggart et al., 2012): Understanding the characteristics of the patient population and applying appropriately supportive and coping strategies may facilitate better engagement or successful compliance with clinical interventions such as PR.

According to Sheridan et al. (2011), psychological factors are presumed to play a role in patients' self-management and influence the degree to which individuals can improve personal skills and knowledge. Identifying patients with high levels of emotional dysfunction at baseline, which this programme of study has shown are less likely to complete the PR programme, and supporting them appropriately, may enable these patients to complete the programme, therefore increasing their chances of acquiring skills to optimise the management of their condition. There is a growing body of recommendations for pre-intervention identification of vulnerable or high risk COPD patients; Ritter and Lorig (2014) suggest screening patients to determine which patients are most in need of interventions designed to enhance self-efficacy. A systematic review

of educational programmes in COPD management interventions by Stoilkova et al. (2013) suggest pre-intervention testing of personality traits, patient's comprehension, attitudes and self-efficacy may provide an opportunity for development of individually tailored programmes based on findings by Gallefoss (2004) and Bourbeau and Nault (2007).

The identification of self-management as running parallel to a continuum of care by Wagg (2012) goes one step further to suggest that the level of support provided for COPD patients as part of a self-management strategy should be based upon the individual patient's need. Based on those findings, it would seem prudent that a flexible multi-component strategy of varying content, duration and intensity would be the appropriate approach to support patients as their requirements escalate or de-escalate. For example, less severe or asymptomatic patients could be provided with a simple, more lifestyle and health promotion orientated approach with support that can be increased or decreased depending on need, while more symptomatic patients are managed with a more clinically orientated model of care that would better suit their medical needs.

The clinical relevance of this approach is described by Wang et al. (2013) who found that a Health Belief Model (HBM) based intervention significantly increased health belief and self-efficacy in patients with moderate to severe COPD. The HBM, initially proposed by Hoch-Baum in the 1950s and can be useful in predicting individual preventative health behaviours and to implement health education (Schofield et al., 2007). The HBM has been widely examined in other chronic conditions such as diabetes (Hazavehei et al., 2007) and osteoporosis (Nieto-Vasquez et al., 2009) with positive health outcomes being demonstrated. According to Wang et al. (2013), previous studies in COPD patients, reported that health belief was related to preventative health behaviours such as smoking cessation and compliance with medication (Schofield et al., 2007 and Nieto-Vasquez et al., 2009). Appropriate implementation of health education based on HBM intervention could not only promote individual preventative health behaviours but also increase quality-of-life. Glanz et al. (2008), describes the behavioural change process that commences when the individual regards themselves as susceptible to a risk condition and believes that the available course of actions is beneficial to their condition, they are more likely to take actions to reduce the risks.

In viewing the Liverpool PR self-management education strategy in the context of HBM, establishing a baseline for clinical outcomes such as, emotional functioning, functional capacity and self-management ability, identifying gaps in the patient's knowledge and any skill deficits will enable the patient to increase their knowledge of their disease,

understand symptoms, implications for treatment and prognosis, which would motivate or facilitate compliance with medical regimen. Lee et al. (2013) also supports this strategy and suggests that identifying characteristics that could predict low levels of self-efficacy would provide essential screening tools for vulnerable patients with COPD, which guide proactive intervention.

6.6 IMPLICATIONS FOR RESEARCH

Reviewing this strategy in the context of the four different phases in MRC Framework (Development, Feasibility, Implementation and Evaluation - see Figure 1.2, Page 42), it is not challenging to identify appropriate points where the findings from this programme of study could potentially inform the design of future PR interventions that are effective.

Development

Findings from evaluation of the Liverpool PR intervention can inform the development phase for developing a complex intervention. For example, Stoilkova et al. (2013) found that lowering patients' barriers through scheduling appointments at convenient times, transportation or improved communication via repeated phone calls and increasing patients' convenience to participate in a programme may result in increased reach of an intervention. Further research into pre-intervention assessment and how the appropriate implementation of the self-management education strategy can be applied to meet the patient's needs is required to further explore this aspect of PR intervention.

Complex interventions have several dimensions of complexity such as variations in the number of intervention components, behaviours and degree of flexibility required to implement it, the groups it targets and the interactions between components (Craig et al., 2008). This could lead to the development of a patient-centred menu-based PR intervention strategy, as proposed by Chaplin et al. (2017) and that will have similarities to those which have been essential in improving uptake and completion rates in cardiac rehabilitation (British Association for Cardiovascular Prevention and Rehabilitation - BACPR, 2012). Gaining a greater understanding of patients' educational needs will enable the design of programmes to include the requirements of patients, in a format that is beneficial (Wilson et al., 2007) for the developmental phase outlined in the MRC Framework. In the context of the MRC framework, the findings of this programme of study contributes to the body of evidence about COPD self-management education incorporated into PR by providing insight to how it works in practice. It also identifies weaknesses in current design (Moore et al., 2015) and provides data on the evaluation of the impact of this intervention on health and other outcomes, which may inform the design of further research studies and future PR services.

Feasibility

Findings from the retrospective study (Chapter Three) and the prospective study (Chapter Five) provide valuable information about testing procedures, such as choice of outcome measures used, estimating sample size, recruitment and retention estimates, which can be used when evaluating feasibility (Philips and Smith, 1993). The results from this programme of study suggest that there are demographic and clinical differences between COPD patients who attend and complete PR and those who do not. Understanding the potential predictors of this behaviour through research may have cost and health outcome benefits for this patient group. In addition, further exploration of self-management from patients' and the health professional's perspective can serve to enhance the data on self-management incorporated into PR. This recommendation is consistent with the outline provided by the MRC Framework for developing and evaluating complex studies. This recommends that ensuring strict standardisation may be inappropriate, i.e., the intervention may work better if a specified degree of adaptation to local settings is allowed for in the protocol Further exploration of how these characteristics and variations may be used to develop bespoke programmes of care that meet patient's individual health and interventions to improve adherence to those programmes, also needs requires further research: There is the need for some qualitative work to explore barriers to individual patients completing self-management interventions incorporated into PR and further exploration of potential facilitators that may enable patients complete these programmes. This process may include a mixture of developing bespoke programmes and introducing interventions that may help adherence.

Implementation

The potential benefits of using self-management as part of PR intervention is currently unknown due to the lack of evidence and consistent findings; further research in this aspect of COPD care would enable the development of a sufficient body of evidence to make recommendations for practice. The MRC Framework substantiates this recommendation for further research by describing how variability in individual level outcomes may reflect higher level processes; sample sizes may need to be larger to take account of the extra variability and cluster randomised designs considered (Craig et al., 2008; 2013).

Although the UCOPD has been identified as being the strongest measure of self-management out of the three measures used in this programme of study, its use in other respiratory patient groups through the development and validation of a modified scale will require further research. The complexity of the concept of self-management and its different constructs and its relationship with health outcomes, does not lend itself to

assessment with a single primary outcome (Craig et al., 2008; 2013). Further research will be required to ascertain weither a range of measures will be needed and to determine what these are for self-management education incorporated into PR. In this case, a single measure for self-management in this patient group may not be as appropriate as a range of measures such as those used in the prospective study being used in conjunction with other measures such as quality of life, health care utilisation and number of exacerbations.

The findings of this programme of study highlights that the PR guidelines require updating to include other aspects of PR such as self-management that may benefit PR patients. Effing et al. (2012), Benzo et al. (2013) and Stoilkova et al. (2013) concluded that publications on COPD self-management interventions lack detailed description of intervention content and process. Further research and update of clinical guidelines to enable clinicians to utilise this strategy effectively would be required to inform not only the design of future PR services but associated implementation strategies, including training of clinicians to implement the intervention. This is to ensure that effective implementation occurs and that these interventions become embedded into practice.

Evaluation

Findings into how the Liverpool PR service works in practice also provides insight into the "Evaluation" phase through the identification of potential outcome measures to assess the effectiveness of the intervention, although more research is required to identify optimal time points for post intervention evaluation (Implementation phase). For example based on the findings of the prospective study, further exploration of the relationship between self-efficacy and other health outcomes such as emotional functioning and how that may evolve over time will inform the design of future study and service design in terms of appropriate assessment points for patients post intervention.

The ability of self-management education as part of PR to effect change is not in dispute, however, there is still uncertainty about what constitutes an optimal PR based self-management intervention, how it effects change, evaluating self-management in COPD, identifying suitable tools to evaluate patient response, identifying appropriate time intervals to measure self-management skill and maintaining improvements gained over time. Research into behavioural change strategies to support the management of complex psychosocial and emotional function in the COPD population is required to provide better insight to this aspect of care. Craig et al. (2008, 2013) in revisiting the 2000 MRC Framework outlined a set of principles for developing and evaluating complex interventions. The first of these principles was, a good theoretical understanding is

needed of how the intervention causes change so that weak links in the causal change can be identified and strengthened. For example, the findings of the retrospective study suggested that change in knowledge did not substantially impact on change in other health outcomes and these findings were supported by the findings from the prospective study, suggesting that further research is needed to establish the path by which change is effected with this intervention in this patient population.

Another potential weak link identified by Kennedy et al. (2014), was that an implementation gap existed between policy aspirations for provision and the delivery of self-management for patients with chronic conditions. Kennedy et al. (2014) identified the lack of guidance or specific detail about how health professionals could change people's behaviour in everyday practice was integral to the failure of an evidence based self-management support strategy for patients in primary care. There is still a lack of consensus regarding what particular skill development activities should be included in self-management programmes (Stellefson et al., 2012), indicating that more research is required to explore the impact of different approaches and components of self-management to form recommendations for practice. It is also important to note that the importance of individual components of self-management in COPD are still unclear (Khan et al., 2017), including how disease-specific behavioural change models can be incorporated into routine interventions. Further research to better understand how self-management works in the management of COPD would be vital to inform the design of future PR services, construct effective interventions, identify appropriate outcome measures and define the intervention in a standardised way. Although the standardisation of the intervention can make certain aspects easier to define, hence making the intervention more widely applicable in a standardised manner, sufficient flexibility to enable adaptation of the intervention to the personal needs of individual patients and, where necessary, to the needs and structure of different services is required for successful implementation (Chaplin et al., 2017). This is consistent with the second principle of developing and evaluating complex studies using the MRC Framework (Craig et al., 2008; 2013) which identified that in in developing a complex intervention, the changes that are expected and how change is to be achieved may not be clear at the onset (Craig et al., 2008). The lack of effect may reflect implementation failure rather than genuine ineffectiveness and recommends that thorough process evaluation is needed to identify implementation problems (Craig et al., 2008; 2013). However, in the same revisit of the 2000 MRC Framework, Craig et al., (2008 and 2013), make it clear that although, understanding processes is important in the development of a complex intervention, it does not replace evaluation of outcomes.

In the context of the MRC framework for complex interventions, the findings of this programme of study can be viewed as contributing towards informing the development phase for a complex intervention. This programme of study has identified and reviewed the evidence base relevant to the incorporation of self-management into PR for patients with COPD and developing an applicable theory through the findings from the analysis of health outcomes and self-management measures. However, further research into the development and feasibility assessment of a standard menu-based approach across different PR services is required to progress this area of research forward. From the findings of this programme of study, it is clear that further exploration of testing procedures for this complex intervention such as appropriate outcome measures and appropriate testing intervals is still required. Although some of the study findings can be viewed as providing insight into the assessment of the Liverpool PR programme's effect on health outcomes and self-management, the mechanism by which this change occurs is still unclear and cost analysis of this intervention was not carried out. These identified gaps need to be addressed through further research before an evaluation phase for the intervention can be planned. The findings of this programme of study can contribute to the current evidence base on self-management in PR and can be used to inform the design of further studies to further explore this phenomenon and construct a framework, such as a toolkit by which an implementation strategy to standardise care can be developed.

6.7 IMPLICATIONS FOR CLINICAL PRACTICE

Understanding of the causal assumptions underpinning the intervention and the use of evaluation to understand how interventions work in practice are vital in building an evidence base that informs policy and practice (Craig et al., 2008; Moore et al., 2015). The importance of understanding the patient population in order to implement appropriate strategies cannot be underestimated. The clinical implications of the characteristics of the study cohort, especially with regard to identifying issues such as emotional dysfunction, poor knowledge and self-efficacy at baseline may enable clinicians to adapt their approach to addressing those potentially limiting issues pre-intervention. Proactive management of these issues may place patients in a better position to engage with clinical intervention and comply with medical regimen to optimise management of their condition. This in turn may translate into improved engagement and completion rates for PR. Another issue highlighted were the possible barriers to completing PR, which included access to transport, parking and the times of PR sessions. The considerations of these factors in the future design of PR services may also serve to support patients to engage and complete their rehabilitative process by providing access to appropriate modes of PR at suitable times. There is also a

suggestion that a single measure in isolation may not provide a comprehensive picture of self-management ability. Clinical guidelines to standardise a comprehensive PR strategy to optimise COPD management through the appropriate evaluation of measures of self-management, will enable the design of effective interventions for COPD patients: The development of a fully comprehensive PR toolkit, which includes self-management, may be the next phase of evolution for PR services.

Health professionals' expectations for patients assuming the responsibility for managing their health have outpaced health professionals' understanding of how to assist them to acquire the knowledge, skills and social facilitation for self-management (Ryan and Sawin, 2009). In order for self-management strategies to be used effectively in practice, self-management of chronic disease by providing training for health professionals (Zwar et al., 2006). Formal self-management programmes are only one strategy in developing self-management and that a person's optimal self-management may require the repeated provision of information and skill development over many years (Glasgow et al., 2003). This notion lends support to the need for training on self-management for chronic conditions for future healthcare workforce, ensuring that chronic disease self-management support can be provided in a sustainable way across the patient's lifespan. The results of the survey study on self-management in PR services across the North West demonstrate that clinical staff have differing ideas on how self-management in COPD patients is measured. Having a better understanding of the concept of COPD self-management and how it can or should be incorporated in PR for COPD patients may further improve the impact of the PR intervention on health outcomes for patients attending these programmes. Further research is required to map the gaps in knowledge and understanding of self-management among clinical staff in order to develop training programmes for staff to develop appropriate self-management support skills.

There is increased awareness of the need to promote conceptual clarity regarding self-management and its integration into clinical practice but equally important is the requirement to develop more sophisticated models of self-management tailored to various health conditions and situations (Grady and Gough, 2014). Fundamental to the development of such models and their practical application is the need to conduct research that informs self-management practice and contributes to health policy, especially as the concept of self-management and its practice is changing (Anderson and Funnell, 2000; Grey et al., 2006; Grady and Gough, 2014).

6.8 THE RIPPLE EFFECT: THE IMPACT OF THE RESEARCH PROGRAMME OF STUDY ON THE LIVERPOOL PR SERVICE

The findings of this programme of study have demonstrated that functional capacity, respiratory disability, emotional functioning and self-management improve post PR intervention in patients with COPD. This section will describe the impact of the research programme of study on the clinical team and their practice.

Benefits of Research

The initial stage of the PhD studentship entailed writing a research proposal, the literature review from the research proposal was utilised to inform the design for an integrated COPD service for Knowsley PCT. The findings of this programme of studies have enabled successful negotiation and renewal of the SLA (year on year from 2010 till 2017, including the first block contract for three years with an extension for an additional two-year period).

In addition presentation of the health outcomes data supported the securement of funding for nine additional members of clinical staff (Bands 2 - 7), funding to increase clinic facilities from 5 community based clinics and 1 hospital based clinic to 7 community based clinic and doubling of the hospital based clinic facility for complex COPD patients, negotiation of a favourable outcomes based tariff per patient based on the health outcomes and securement of £20,000 to fund the development of a web-based and interactive augmented reality tool to further support the current PR self-management education strategy and to roll out to patients who traditionally have not engaged with the rehabilitative process.

Evidence Based Practice

The survey of 24 Primary Care Trusts in the North West of England enabled the Liverpool PR service to be benchmarked against other services in the region, which served as quality assurance for the service and has assisted the negotiation of new contracts with the commissioners. The retrospective analysis of the health outcomes from the PR database provided the team with an opportunity to accrue valuable data collation, recording and analytical skills which have enabled the team to secure increased investment and resources to provide increased and more equitable coverage across the 17 different neighbourhoods in Liverpool. This analysis of post intervention data has also resulted in the validation of brief interventions for patients who are unable to complete the full programme but their health outcomes data demonstrates that these patients can benefit from the application of appropriate modes of treatment specifically tailored to address identified patient needs. As a result, targeted intervention has

become a validated programme of care, which is funded by the Liverpool Clinical Commissioning Group (LCCG) as part of the Pulmonary Rehabilitation programme.

This evolutionary process has enabled the team to share lessons learnt and good practice with colleagues in the region, either locally through joint work or informal peer work or through presentations at NHS Research or clinical conferences. Joint work with Liverpool CCG in COPD insight project with Public Health Liverpool and using the self-management education strategy utilised in PR to develop a similar resource for newly diagnosed COPD patients in primary care.

Change in Practice

The findings of the retrospective study also flagged up a potential flaw in the heterogeneous method applied to the measurement of functional capacity through the use of the Six Minute Walk Test and the Incremental Shuttle Walk test. Standardisation of the walk test to the Six Minute Walk Test from 1/04/2015, which has enabled the team to work better with other respiratory services such as the oxygen service that utilise the same test to reduce the burden on patients through duplicate tests and to monitor the management or progress of patients with chronic lung disease who are on long term or ambulatory oxygen over time.

In addition, the results of the analysis of the patient demographic information from the second PhD study has enabled the team in conjunction with LCCG to better understand the COPD trends in Liverpool. These results informed the design of strategies to engage patient groups that tend not to engage or complete Pulmonary Intervention (younger patients, patients with mild COPD, poorer patients and current smokers). The team was able to formalise links with agencies such as the North West Ambulance service for logistical support to transport patients to the programme, the Liverpool FagEnds service for smoking cessation support, the Breatheasy support groups from the British Lung Foundation for ongoing patient support and other agencies such as the Healthy Homes scheme for environmental or domestic related support or Talk Liverpool for psychological support.

Quality assurance measures have been introduced as a direct result of lessons learnt from the second PhD study: The potential for errors in the health outcomes database was identified during the data extraction phase of the second study. Quality assurance measures were introduced to ensure that data was complete and correct at the assessment stage in clinic, a second check was carried out by the data input clerk and a final assurance check is carried out before the clinical case notes for that patient are

closed. The introduction of these quality assurance measures enabled the team to meet all quality assurance indicators outlined in the new SLA and pass the quality assurance checks by the LCCG Intelligence team. This level of quality assurance ensured that the validity of the health outcomes data and evaluation of the impact of the team's intervention is a significant part of the COPD management strategy for LCCG and has resulted in joint working with Public Health Liverpool on the COPD Insight project.

The information on barriers to PR completion was used to inform the choice of the two new community-based PR clinics which had free parking, easy access to public transport. The days and times of PR clinics were also amended to provide a range of days and times where patients could access the PR service at different sites across the city. In addition, a second hospital-based assessment clinic was developed with earlier times to suit needs of patients on oxygen or more severe category disease who required assistance with transport but did not want a late drop off time (which tended to occur with the pre-existing clinic time), patients with childcare commitments or work commitments.

Research Culture

The results of the second PhD study showed that although Pulmonary Rehabilitation improved functional capacity measures, the improvement was not maintained over time. The "NaJo" project was a pilot project the team developed in response to this phenomenon with the hypothesis that the loss of the benefits from the programme may have been due to natural attrition as patients stopped exercising regularly once they finished the programme, however, if patients had a well-structured and bespoke home exercise programme with exercise or activity monitoring in situ, this may result in more patients maintaining a higher frequency of independent exercise. The NaJo home exercise dairy was designed by two members of the team (Nathan Hilton and Josie Thorn) in collaboration with the rest of the team and the results of the pilot supported the hypothesis. The preliminary results indicated that patients can be encouraged to maintain an effective post programme exercise with the right regimen. The outcome of this pilot study has been the successful incorporation of the NaJo diary into routine practice.

In order to further consolidate "on the job" research training, the team is working in partnership with the MRHA Research Unit at the Royal Liverpool and Broadgreen Hospital on the C4C project. Team members have also commenced research related study such as Good Clinical Practice (GCP) training to further improve their research skills. Research projects that the team has been able to participate in as a result of the research skills include, the RCP Patient Reported Measures (PREMs) audit, the National

BTS COPD pilot audit, the annual national BTS COPD audit, the NaJo project and a RCT on the effect of PR on outcomes for patient with Endobronchial valves. Other projects proposed are analysis of health outcomes for patients with interstitial lung disease and the development of an appropriate self-management assessment tool. In addition to these, the team is currently in the process of working in partnership with Public Health Liverpool on a COPD insight project.

The acquisition of data collection, data handling and analysis skills from the PhD programme of studies has been shared with the team. Over the last two years of this programme of studies, the collective analysis of referral, attendance and health outcomes data has become part of routine practice for the team and from 2015, the PR attendance and health outcomes data were used as the basis to set team objectives to plan for the year ahead with full participation from the entire team. Improved collective understanding of the trends from the data collected as part of routine clinical practice has enabled the team to be more effective in the response to the needs of the local COPD population and to apply effective evidence based strategies to address these needs.

Change of Culture

Being able to share these successes both individually and as a team, to reflect on the team's achievements as well as to strategise as a team on how to further improve knowledge, expertise and impact of intervention has become part of routine practice. This has proven to be a successful motivational tool to strive for higher standards of practice with better health outcomes for patients attending the programme. The engagement of the whole team at midyear and end of year service evaluation has been an unexpected outcome of this PhD programme of studies. It has also resulted in the whole team demonstrating a sense of ownership for the data, a communal sense of responsibility for health outcomes and an enthusiasm for engaging in further research to continue to improve our practice. The narrative of this evolutionary process, change in practice and cultural change has been shared regionally through the North West NHS Research collaborative which chose it as an illustration of good clinical research practice for 2015/2016 (Appendix 30) and nationally with the Chartered Society of Physiotherapy sharing the developments, achievements and lessons learnt as good innovative clinical practice in 2015 (Hunt, 2015 – see Appendix 31).

6.9 THE NEXT STEPS

The next step would entail the dissemination of the findings from the three studies through presentations and publications such as the Physiotherapy Journal, COPD: Journal of Chronic Obstructive Pulmonary Disease, the British Medical Journal (BMJ),

the Patient Education and Counselling journal and the Respiratory journal for fellow clinicians and researchers. Although no study participants signed up for a newsletter, a summary report of the findings will be produced for the Liverpool PR service website (Breathe website). In addition to this, the research student intends to share the findings of the study, lessons learnt and recommendations for practice with the clinical team and the Liverpool commissioners. The research student also intends to carry out post-doctoral analysis of the PR data and contribute to an ongoing project in conjunction with the Liverpool commissioners to inform the redesign of respiratory and cardiac services on Merseyside.

The research student intends to continue with further research to explore the development of self-management skills within this patient group with longer follow-up time to investigate the trends demonstrated with regard to self-efficacy and behavioural change. Part of this will entail exploring strategies to facilitate engagement with the groups that tend not to complete the programme, including exploring avenues for pre-rehab strategies.

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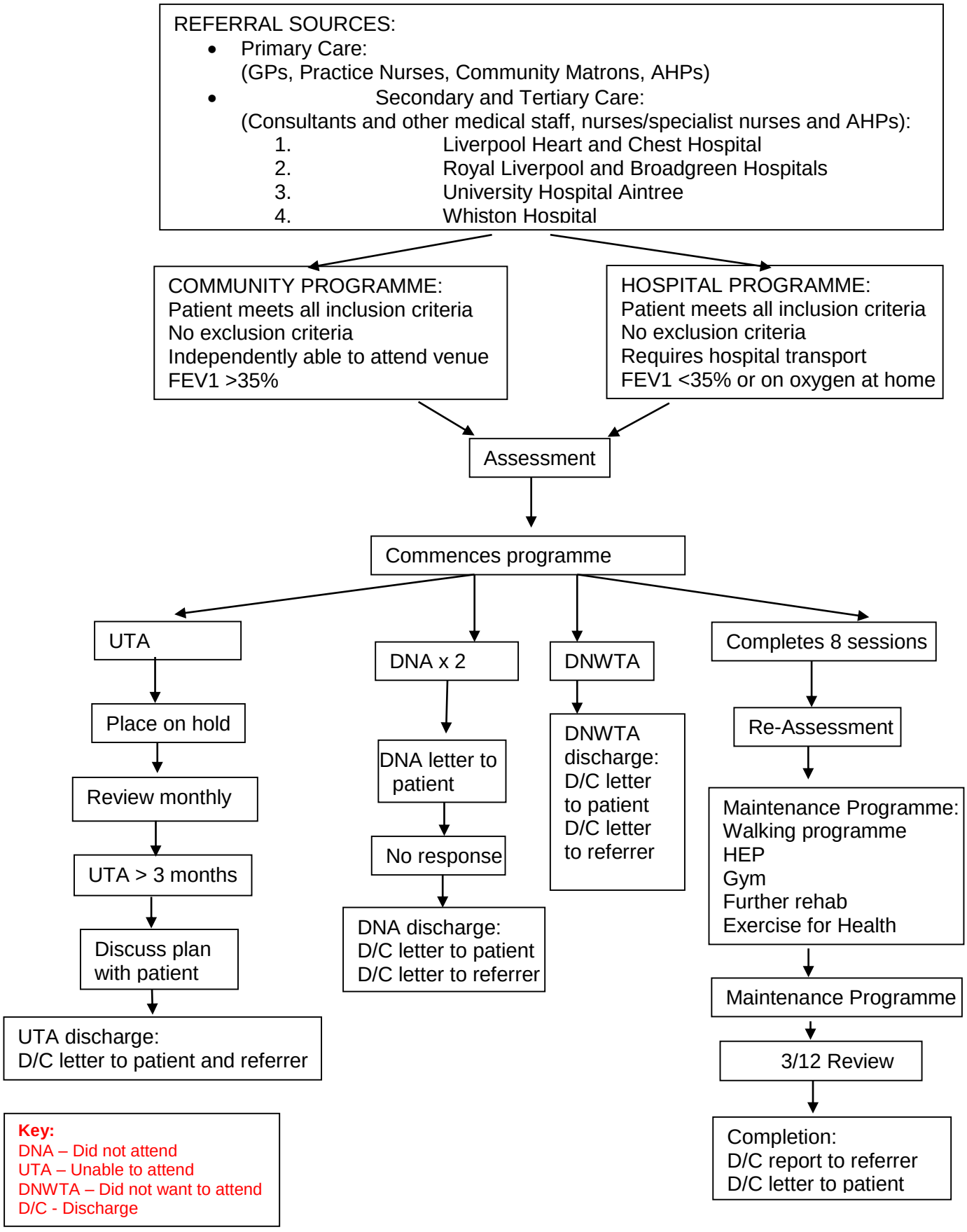
APPENDICES

Appendix 1

PULMONARY REHABILITATION SERVICE MODEL



Appendix 2 – Shuttle Walk Test (SWT)

	INTIAL ASSESSMENT	
	Pre-shuttle	**Post shuttle**
HR		
BP		
SpO2		
BORG		

INITIAL ASSESSMENT				
Level	**Shuttles**	**Total distance**	**SpO2**	**HR**
1	**1 2 3**	30		
2	**4 5 6 7**	70		
3	**8 9 10 11 12**	120		
4	**13 14 15 16 17 18**	180		
5	**19 20 21 22 23 24 25**	250		
6	**26 27 28 29 30 31 32 33**	330		
7	**34 35 36 37 38 39 40 41 42**	420		
8	**43 44 45 46 47 48 49 50 51 52**	520		
9	**53 54 55 56 57 58 59 60 61 62 63**	630		
10	**64 65 66 67 68 69 70 71 72 73 74 75**	750		
11	**76 77 78 79 80 81 82 83 84 85 86 87 88**	880		
12	**89 90 91 92 93 94 95 96 97 98 99 100 101 102**	1020		

	INITIAL ASSESSMENT
LEVEL ACHIEVED	
TOTAL SHUTTLES	
TOTAL DISTANCE (m)	
REASON FOR STOPPING: **1. > 80% HRR** **2. Fatigue (pace)** **3. SOB** **4. SpO2 ↓ >5%** **5. Other (please comment)**	

Appendix 3 - Hospital Anxiety and Depression Scale (HADS)

Chart 1 – Hospital Anxiety and Depression Scale

This questionnaire will help your physician to know how you are feeling. Read every sentence. Place an "X" on the answer that best describes how you have been feeling during the LAST WEEK. You do not have to think too much to answer. In this questionnaire, spontaneous answers are more important.

A 1) I feel tense or wound up:
- 3 ( ) Most of the time
- 2 ( ) A lot of the time
- 1 ( ) From time to time
- 0 ( ) Not at all

D 2) I still enjoy the things I used to enjoy
- 0 ( ) Definitely as much
- 1 ( ) Not quite so much
- 2 ( ) Only a little
- 3 ( ) Hardly at all

A 3) I get a sort of frightened feeling as if something awful is about to happen
- 3 ( ) Very definitely and quite badly
- 2 ( ) Yes, but not too badly
- 1 ( ) A little, but it doesn't worry me
- 0 ( ) Not at all

D 4) I can laugh and see the funny side of things
- 0 ( ) As much as I always could
- 1 ( ) Not quite as much now
- 2 ( ) Definitely not so much now
- 3 ( ) Not at all

A 5) Worrying thought goes through my mind
- 3 ( ) A great deal of the time
- 2 ( ) A lot of the time
- 1 ( ) From time to time but not too often
- 0 ( ) Only occasionally

D 6) I feel cheerful
- 3 ( ) Not at all
- 2 ( ) Not often
- 1 ( ) Sometimes
- 0 ( ) Most of the time

A 7) I can seat at ease and feel relaxed
- 0 ( ) Definitely
- 1 ( ) Usually
- 2 ( ) Not often
- 3 ( ) Not at all

D 8) I feel as I am slowed down
- 3 ( ) Nearly all the time
- 2 ( ) Very often
- 1 ( ) Sometimes
- 0 ( ) Not at all

A 9) I get a sort of frightened feeling like butterflies in the stomach
- 0 ( ) Not at all
- 1 ( ) Occasionally
- 2 ( ) Quite often
- 3 ( ) Very often

D 10) I have lost interest in my appearance
- 3 ( ) Definitely
- 2 ( ) I don't take so much care as I should
- 1 ( ) I may not take quite as much care
- 0 ( ) I take just as much care as ever

A 11) I feel restless, as if I had to be on the move
- 3 ( ) Very much indeed
- 2 ( ) Quite a lot
- 1 ( ) Not very much
- 0 ( ) Not at all

D 12) I look forward with enjoyment to things
- 0 ( ) As much as I ever did
- 1 ( ) Rather less than I used to
- 2 ( ) Definitely less than I used to
- 3 ( ) Hardly at all

A 13) I get sudden feeling of panic
- 3 ( ) Very often indeed
- 2 ( ) Quite often
- 1 ( ) Not very often
- 0 ( ) Not at all

D 14) I can enjoy a good TV or radio program or book
- 0 ( ) Often
- 1 ( ) Sometimes
- 2 ( ) Not often
- 3 ( ) Very seldom

Appendix 4 – Bristol COPD Knowledge Questionnaire (BCKQ)

NHS BRISTOL COPD KNOWLEDGE QUESTIONNAIRE (BCKQ)©

Name: _____ **Date:** _____

This questionnaire is designed to find out what you know about your lung problem. It should be completed without help from anyone else. This usually takes between 10 and 20 minutes. Your answers will help us to find out what information you need to help you to understand and manage your lung condition.

Mark the circle which you think is the correct answer.

		True	False	Don't Know
1	**In COPD:**			
a	In COPD the word "chronic" means it is severe.	○	○	○
b	COPD can only be confirmed by breathing tests.	○	○	○
c	In COPD there is usually gradual worsening over time.	○	○	○
d	In COPD oxygen levels in the blood are always low.	○	○	○
e	COPD is unusual in people less than 40 years old.	○	○	○
2	**COPD:**			
a	More than 80% of COPD cases are caused by cigarette smoking.	○	○	○
b	COPD can be caused by occupational dust exposure.	○	○	○
c	Longstanding asthma can develop into COPD	○	○	○
d	COPD is commonly an inherited disease.	○	○	○
e	Women are less vulnerable to the effects of cigarette smoking than men.	○	○	○
3	**The following symptoms are *COMMON* in COPD:**			
a	Swelling of ankles	○	○	○
b	Fatigue (tiredness)	○	○	○
c	Wheezing	○	○	○
d	Crushing chest pain	○	○	○
e	Rapid weight loss	○	○	○
4	**Breathlessness in COPD:**			
a	Severe breathlessness prevents travel by air.	○	○	○
b	Breathlessness can be worsened by eating large meals.	○	○	○
c	Breathlessness means that your oxygen levels are low.	○	○	○
d	Breathlessness is a normal response to exercise.	○	○	○
e	Breathlessness is primarily caused by a narrowing of the bronchial tubes.	○	○	○

5	Phlegm (sputum):	True	False	Don't Know
a	Coughing phlegm is a common symptom in COPD	○	○	○
b	Clearing phlegm is more difficult if you get dehydrated.	○	○	○
c	Bronchodilator inhalers can help clear phlegm.	○	○	○
d	Phlegm causes harm if swallowed.	○	○	○
e	Clearing phlegm can be assisted by breathing exercises.	○	○	○

6	Chest infections / exacerbations:	True	False	Don't Know
a	Chest infections often cause coughing of blood.	○	○	○
b	With chest infections phlegm usually becomes coloured (yellow or green).	○	○	○
c	Exacerbations (episodes of worsening) can occur in the absence of a chest infection.	○	○	○
d	Chest infections are always accompanied by a high temperature.	○	○	○
e	Steroid tablets should be taken whenever there is an exacerbation.	○	○	○

7	Exercise in COPD:	True	False	Don't Know
a	Walking is better exercise than breathing exercises to improve fitness.	○	○	○
b	Exercise should be avoided as it strains the lungs.	○	○	○
c	Exercise can help maintain your bone density.	○	○	○
d	Exercise helps relieve depression.	○	○	○
e	Exercise should be stopped if it makes you breathless.	○	○	○

8	Smoking:	True	False	Don't Know
a	Stopping smoking will reduce the risk of heart disease.	○	○	○
b	Stopping smoking will slow down further lung damage.	○	○	○
c	Stopping smoking is pointless as the damage is done.	○	○	○
d	Stopping smoking usually results in improved lung function.	○	○	○
e	Nicotine replacement therapy is only available on prescription.	○	○	○

9	Vaccination:	True	False	Don't Know
a	A flu jab is recommended every year.	○	○	○
b	You can get flu from having a flu jab.	○	○	○
c	You can only have a flu jab if you are 65 or over.	○	○	○
d	A pneumonia jab protects against all forms of pneumonia.	○	○	○
e	You can have a pneumonia jab and a flu jab on the same day.	○	○	○

10	Inhaled brochodilators:	True	False	Don't Know
a	All bronchodilators act quickly (within 10 minutes).	○	○	○
b	Both short and long acting bronchodilators can be taken on the same day.	○	○	○
c	Spacers (e.g. volumatic, nebuhaler, aerochamber) should be dried with a towel after washing.	○	○	○
d	Using a spacer device will increase the amount of drug deposited in the lungs.	○	○	○
e	Tremor may be a side effect of bronchodilators.	○	○	○

11	Antibiotic treatment in COPD:	True	False	Don't Know
a	To be effective, the course should last at least 10 days.	○	○	○
b	Excessive use of antibiotics can cause resistant bacteria (germs).	○	○	○
c	Antibiotics will clear all chest infections.	○	○	○
d	Antibiotic treatment is necessary for an exacerbation (worsening) however mild.	○	○	○
e	You should seek advice if antibiotics cause severe diarrhoea.	○	○	○

12	Steroid tablets given for COPD (eg Prednisolone):	True	False	Don't Know
a	Steroid tablets help strengthen muscles.	○	○	○
b	Steroid tablets should be avoided if there is a chest infection.	○	○	○
c	The risk of long-term side effects due to steroids is less with short courses than with continuous treatment.	○	○	○
d	Indigestion is a common side effect from using steroid tablets.	○	○	○
e	Steroid tablets can increase your appetite.	○	○	○

13	Inhaled steroids (brown, red or orange):	True	False	Don't Know
a	Inhaled steroids should be stopped if you are given steroid tablets.	○	○	○
b	Steroid inhalers can be used for rapid relief of breathlessness.	○	○	○
c	Spacer devices reduce the risk of getting thrush in the mouth.	○	○	○
d	Steroid inhaler should be taken before your bronchodilator.	○	○	○
e	Inhaled steroids improve lung function in COPD.	○	○	○

Further supplies can be obtained from:
Department of Medicine (BCKQ)
Frenchay hospital,
Bristol BS16 1LE

Ref.: White R, Walker P, Roberts S, Kalisky S, White P,
Chronic Respiratory Disease. 2006;3:123-131

Designed by the Medical Illustration Department, Frenchay Hospital, Bristol

Appendix 5 – Ethics Email (Survey Study)

From: Perez-Casal Margarita
Sent: Wednesday 06 April 2011 08:49
To: Gana Joy
Subject: RE: UCLan Query

Joy, if you are not contacting patients and you are only capturing information that is already captured for routine use, you don't need ethics.
In a way we would see this as a service evaluation, and those do not require ethics.
I hope this clarifies matters.
BW,
Marga

Dr Margarita Perez-Casal
Research, Audit and Effectiveness Manager
Department of Clinical Quality
Liverpool Heart and Chest Hospital NHS Foundation Trust
Thomas Drive
Liverpool L14 3PE

E-mail: Margarita.Perez-Casal@lhch.nhs.uk
Direct line: 0151 6001467
Secretary: 0151 6001370

From: Gana Joy
Sent: Wednesday 06 April 2011 08:42
To: Perez-Casal Margarita
Subject: FW: UCLan Query

Hi Marga
I'm awfully sorry to bother you but Prof Dey has asked me to confirm that the pulmonary rehab services survey does not require NHS ethics approval. The survey is a telephone interview with PR leads using a questionnaire designed to capture information regarding the format of PR programmes based in the North West of England. Many thanks.

Kind Regards,

Joy

Joy Gana-Inatimi
Clinical Lead Chest Medicine, Pulmonary Rehabilitation and Training/Education
The Liverpool Heart and Chest Hospital NHS Foundation Trust

☎ 0151 228 1616 Bleep 2160
Fax. No. 0151 600 1659
joy.gana@lhch.nhs.uk

Appendix 6 – UCLAN Ethics Approval (Survey)

22nd July 2011

Paola Dey/Joy Gana-Intami/Chris Sutton/H Stewart
School of Postgraduate Medical & Dental Education
University of Central Lancashire

Dear Paola, Joy & Chris

Re: Faculty of Health & Social Care Ethics Committee (FHEC) Application - (Proposal No.504)

The FHEC has granted approval of your proposal application 'The impact of Pulmonary rehabilitation self – management education on outcomes in patients with COPD – Pulmonary rehabilitation services survey' on the basis described in its 'Notes for Applicants'.

We shall e-mail you a copy of the end-of-project report form to complete within a month of the anticipated date of project completion you specified on your application form. This should be completed, within 3 months, to complete the ethics governance procedures or, alternatively, an amended end-of-project date forwarded to Research Office.

Yours sincerely

Miltos Ladikas
Deputy Vice Chair
Faculty of Health Ethics Committee

Appendix 7 - Pulmonary Rehabilitation Service Pre-Pilot Study Questionnaire

SCHOOL HEADED PAPER

Study Number:……..
Principal Investigator: Joy Gana-Inatimi

Pulmonary Rehabilitation Service Pre-Pilot Study Questionnaire

Thank you for your help with this questionnaire. I will be phoning you soon to go through the questions. The purpose of this questionnaire is to gather information regarding the provision of pulmonary intervention for patients with COPD patients across the North West of England. Your responses will be used to create a description of the availability and distribution of pulmonary rehabilitation service based in the North West as part of a University of Central Lancashire PhD project investigating the impact of pulmonary rehabilitation intervention on COPD patients.
You may wish to spend some time going through the questions in preparation for my telephone call. If after reading the questionnaire, you no longer wish to take part, please contact me by email

1. In what type of NHS organisation is the pulmonary rehabilitation service based?
   Please tick only one option
   a) Primary Care □
   b) Secondary Care □
   c) Tertiary Care □
   d) Other □
   If other, please tell me what type of organisation
   .....

2. What groups of health professionals are involved in the day to day delivery of your programme? Please tick as many options that are applicable
   a) Physiotherapist □
   b) Exercise Physiologist □
   c) Nurse □
   d) Pharmacist □
   e) Doctor □
   f) Dietician □
   g) Occupational Therapist □
   h) Psychologist □
   i) Other (Please list below) □
   .....
   .....
   .....

3. What type of pulmonary rehabilitation service do you provide?
   Please tick only one option
   a) Hospital based service □
   b) Community based service □
   c) Both Hospital and community based services □

4. Do you provide a service for COPD patients on oxygen?

   Yes □ No □

5. How long is your programme, i.e., number of weeks?
   Please tick only one option
   a) 1 week □
   b) 2 weeks □
   c) 3 weeks □
   d) 4 weeks □
   e) 5 weeks □
   f) 6 weeks □
   g) 7 weeks □
   h) 8 weeks □
   i) 9 weeks □
   j) 10 weeks □
   k) 11 weeks □
   l) 12 weeks □
   m) Other (Please list below) □
   ……

6. How often do patients should attend the sessions?
   Please tick only one option
   a) Once a week □
   b) Twice a week □
   c) Other (Please list below) □
   ……

7. What does your pulmonary rehabilitation programme comprise?
   Please tick only one option
   a) Exercise only □
   b) Education only □
   c) Both Exercise and Education □
   d) Other (Please list below) □

8. Do you provide any home exercises for your patients? If respondent answers No – go to Q11

   Yes □ No □

9. If yes, what do you provide?
   Please tick only one option
   a) Exercise routine □
   b) Exercise routine and equipment □
   c) Other (Please list below) □
   ……

10. How often do you advise patients to carry out their home exercise programme (min frequency)?
    Please tick only one option
    a) Once a week □
    b) Twice a week □
    c) Three times a week □
    d) Alternate days □
    e) Daily □
    f) Other (Please list below) □
    ……..

11. Do you have a formal or structured education component to your pulmonary rehabilitation programme? If respondent answers No – go to Q 14

    Yes □ No □

12. If yes – what topics do you cover?
    Please tick as many options that are applicable
    a) Disease education □
    b) Medication □
    c) Symptom management □
    d) Diet □
    e) Stress management □
    f) Anxiety management □
    g) Energy Conservation □
    h) Exercise □
    i) Smoking cessation □
    j) Environmental Health □
    k) Support services □
    l) Other (Please list below) □

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13. Who deliver(s) the educational component of your programme?
    Please tick as many options that are applicable
    a) Physiotherapist □
    b) Exercise Physiologist □
    c) Nurse □
    d) Pharmacist □
    e) Doctor □
    f) Dietician □
    g) Occupational Therapist □
    h) Psychologist □
    i) Other (Please list below) □

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14. Do you give your patients disease specific education material to take away with them?
    If respondent answers No please go to question 16

    Yes □ No □

15. If yes, what are they and in what format are they?
    Please tick as many options that are applicable
    a) Written □
    b) Audio □
    c) Visual □
    d) Other (please list below) □

……
……
……

16. Do you assess patients' knowledge of their condition? If respondent answers No please go to question 19

    Yes □ No □

17. If yes, what tool or tools do you currently use to do so?
    Please tick as many options that are applicable
    a) Patient feedback (informal) □
    b) Saint Georges Respiratory Questionnaire (SGRQ) □
    c) Lung Information Needs Questionnaire (LINQ) □
    d) Bristol COPD Knowledge Questionnaire (BCKQ) □
    e) Other/Combinations of others (Please list below) □

    ……
    ……
    ……
    …….....

18. Do you re-assess this on completion of your programme? If respondent answers No, the questionnaire is complete

    Yes □ No □

19. Do you routinely follow up patients following completion of pulmonary rehabilitation?

    Yes □ No □

20. If yes, what does your follow up comprise?
    Please tick as many options that are applicable
    a) Telephone follow up □
    b) Face-to-face informal follow up □
    c) Formal reassessment of all parameters assessed previously □
    d) Other (Please list below) □

    ……

21. At what time points do you carry out your follow ups?
    Please tick as many options that are applicable
    a) On completing the programme □
    b) 1 month after completing the programme □
    c) 2 months after completing the programme □
    d) 3 months after completing the programme □
    e) 6 months after completing the programme □
    f) 12 months after completing the programme □
    g) 18 months after completing the programme □
    h) 24 months after completing the programme □
    i) Other (Please list below) □

……
……
…….....

Thank you for taking the time to go through this questionnaire over the telephone.

Appendix 8 – Pre-Pilot Cover Email

Principal Investigator: Joy Gana-Inatimi

Dear Sir/Madam

Re: Pre-pilot Pulmonary Rehabilitation Services Survey

Thank you for taking the time to talk to me earlier on today and for expressing interest in taking part in this survey. Following our telephone conversation, as promised I am forwarding you further information about the survey you are considering taking part in.

As I informed you on the phone, my name is Joy Gana-Inatimi and I am a physiotherapist working in pulmonary rehabilitation. I am currently in the process of studying for a PhD at the University of Central Lancashire. As part of my PhD, I will be carrying out research into the impact of self-management education as part of pulmonary rehabilitation on outcomes for patients with COPD. I am conducting a survey of pulmonary rehabilitation services in the North West of England to identify what educational components are included in their programmes and how outcomes are measured.

I have designed a questionnaire which I plan to use to interview clinical leads for pulmonary rehabilitation services. Before doing this, I need to find out if the questionnaire I have designed covers all the important areas it should and that it is understandable. I would like you to help me with this. This would involve a short 10 to 15 minute telephone call when I would go through the questions with you and ask you to comment on the structure or phrasing of the questions in the questionnaire. You will also be asked what you think I may have missed. I would take notes on what you think of the questions and questionnaire. I would not need to know how you would answer the questions. All information collected as part of this study will be anonymised and will be kept confidential. I attach more information about the study to this email and a copy of the questionnaire for you to look at.

If you are willing to take part in the study, I would be grateful if you could e-mail back to let me know. Once I know that you are willing to take part, I will contact you again to arrange a date/time for a telephone call that is convenient for you in order to go through your answers to the questionnaire.

Thank you for your time. Please do not hesitate to contact me if you have any queries or require further information.

Kind regards

Joy Gana-Inatimi
PhD student and Clinical Lead Physiotherapist for Chest Medicine and Pulmonary Rehabilitation (LHCH)

Contact number: 0151 600 1950
Contact email: JGana-inatimi@uclan.ac.uk

Appendix 9 - Pre-Pilot Study Participant Information Sheet

SCHOOL HEADED PAPER

Study Number:……..
Principal Investigator: Joy Gana-Inatimi

Pre-Pilot Study Participant Information Sheet

You are being invited to take part in a University of Central Lancashire PhD research study into the impact of self-management education as part of pulmonary rehabilitation on outcomes for patients with COPD. As part of the study, a survey of the different outcome measures and education programmes used as part of pulmonary rehabilitation will be carried out across the North West of England.

What is the purpose of the study and why have I been chosen??
The aim of this study is to investigate the impact of disease specific patient education on recorded patient outcome measures and how they help patients manage their condition better over time. You have been contacted because you have been identified as running a pulmonary rehabilitation programme in the North West of England. I have designed a questionnaire which I plan to use to interview clinical leads for pulmonary rehabilitation services but before doing this, I need to find out if the questionnaire I have designed covers all the important areas it should and that it is understandable.

What will happen?
If you agree to participate in the study, the principal investigator will arrange a telephone appointment date and time that is convenient for you to carry out a simple telephone exercise.

What will I be asked to do, if I take part?
You will be asked to go through the questionnaire over the phone with the principal investigator. . You will be asked to think out loud or comment on your opinion of the structure and phrasing of each question as guided by the principal investigator. Your feedback regarding each question and the design of the questionnaire will be documented. The principal investigator will not ask you for answers to the questions. This should only take 10 to 15 minutes.

We will use your thoughts on the questions and question to improve it and it will help ensure that other readers are able to interpret the questions appropriately and that the questionnaire is able to collect the information the study requires.

What if there is a problem?
If you have a concern about any aspect of this study, you should first contact the principal investigator (Joy Gana-Inatimi via e-mail at JGana-inatimi@uclan.ac.uk and by telephone on 0151 600 1950). If you have any remaining concerns, please contact the PhD Director of studies (Professor Paola Dey via email at MPDey@uclan.ac.uk and by telephone on 01772 892782).

Will my taking part in this study be kept confidential?
If you decide to take part, all information that is collected about you during the course of the study will be kept strictly confidential and will remain confidential within the study team. Your comments will be anonymised. Once they are anonymised we cannot identify them and therefore cannot remove them from the study data. You/your organisation will not be able to be identified from any report that is published from this study.

What will happen to the results at the end of the research study?
The results of this study will not be known until sometime after the last organisation taking part in the study has completed their questionnaire as part of the survey and the PhD programme of studies has been completed. The findings will be reported in academic and professional publications or presented at academic or clinical meetings but organisations that have participated in the study will not be identified by name. As a participant, and contributor to the study, you will be sent a copy of the summary of the findings of the study. All the information about your participation in this study will be kept confidential and will be stored for 5 years after finishing the study in a locked cabinet and a password protected and anonymised database following the completion of the study. At the end of 5 years, the questionnaires and the data will be destroyed.

Who is organising and funding the research?
The study is being carried out as part of a PhD studentship project with the University of Central Lancashire and is funded by the North West Strategic Health Authority.

Who has reviewed the study?
The study has been reviewed by the Liverpool Heart and Chest Hospital Research Committee, the allocated supervisory team for the PhD project and the University of Central Lancashire's Ethics Committee.

What do I do now?
Thank you for considering taking part in this study. If you are willing to participate in the study, please e-mail the principal investigator at JGana-inatimi@uclan.ac.uk and you will be contacted by the principal investigator to arrange a telephone appointment with you. Please keep this information sheet for your records so that you can contact the principal investigator (Joy Gana-Inatimi via e-mail at JGana-inatimi@uclan.ac.uk and by telephone on 0151 600 1950) or the PhD Director of studies (Professor Paola Dey via email at MPDey@uclan.ac.uk and by telephone on 01772 892782) if you have any queries or require further information.
If you decide not to participate, thank you for taking the time to read the information I have sent to you. Please let the principal investigator know via e-mail of your decision, so that you are not contacted again regarding the study.

Contact details:

Principal Investigator:
Name: Joy Gana-Inatimi
Address: PhD Student
Postgraduate School of Medical and Dental Education
University of Central Lancashire
Preston, PR1 2HE
E-mail: JGana-Inatimi@uclan.ac.uk
Telephone: 0151 600 1950

Director of Studies:
Name: Professor Paola Dey
Address: Professor of Public Health Epidemiology
Postgraduate School of Medical and Dental Education
University of Central Lancashire
Preston, PR1 2HE
E-mail: MPDey@uclan.ac.uk
Telephone: 01772 892782

Appendix 10 - Pulmonary Rehabilitation Service Pilot Study Questionnaire

SCHOOL HEADED PAPER
Study Number:……..
Principal Investigator: Joy Gana-Inatimi

Pulmonary Rehabilitation Service Pilot Study Questionnaire

Thank you for your help with this questionnaire. I will be phoning you soon to go through the questions. The purpose of this questionnaire is to gather information regarding the provision of pulmonary intervention for patients with COPD patients across the North West of England. Your responses will be used to create a description of the availability and distribution of pulmonary rehabilitation service based in the North West as part of a University of Central Lancashire PhD project investigating the impact of pulmonary rehabilitation intervention on COPD patients.
You may wish to spend some time going through the questions in preparation for my telephone call. If after reading the questionnaire, you no longer wish to take part, please contact me by email

1. In what type of NHS organisation is the pulmonary rehabilitation service based?
   Please tick only one option
   a) Primary Care □
   b) Secondary Care □
   c) Tertiary Care □
   d) Other □
   If other, please tell me what type of organisation .....

2. What groups of health professionals are involved in the day to day delivery of your programme?
   Please tick as many options that are applicable
   a) Physiotherapist □
   b) Exercise Physiologist □
   c) Nurse □
   d) Pharmacist □
   e) Doctor □
   f) Dietician □
   g) Occupational Therapist □
   h) Psychologist □
   i) Other (Please list below) □
   .....
.....

3. What type of pulmonary rehabilitation service do you provide?
   Please tick only one option
   a) Hospital based service □
   b) Community based service □
   c) Both Hospital and community based services □

4. Do you provide a service for COPD patients on oxygen?

   Yes □ No □

5. How long is your programme, i.e., number of weeks?
   Please tick only one option
   a) 1 week □
   b) 2 weeks □
   c) 3 weeks □
   d) 4 weeks □
   e) 5 weeks □
   f) 6 weeks □
   g) 7 weeks □
   h) 8 weeks □
   i) 9 weeks □
   j) 10 weeks □
   k) 11 weeks □
   l) 12 weeks □
   m) Other (Please list below) □
   ……

6. How often do patients have to attend the sessions?
   Please tick only one option
   a) Once a week □
   b) Twice a week □
   c) Other (Please list below) □
   ……..

7. What does your pulmonary rehabilitation programme comprise?
   Please tick only one option
   a) Exercise only □
   b) Education only □
   c) Both Exercise and Education □
   d) Other (Please list below) □

8. Do you provide any home exercises for your patients? If respondent answers no, please move to question 11

   Yes □ No □

9. If yes, what do you provide?
   Please tick only one option
   a) Exercise routine □
   b) Exercise routine and equipment □
   c) Other (Please list below) □
   ……

10. How often do you advise patients to carry out their home exercise programme (min frequency)?
    Please tick only one option
    a) Once a week □
    b) Twice a week □
    c) Three times a week □
    d) Alternate days □
    e) Daily □
    f) Other (Please list below) □
    ……..

11. Do you have a formal or structured education component to your pulmonary rehabilitation programme? If respondent answers no, please move to question 14

    Yes □ No □

12. If yes – what topics do you cover?
    Please tick as many options that are applicable

a)	Disease education	□
b)	Medication	□
c)	Symptom management	□
d)	Diet	□
e)	Stress management	□
f)	Anxiety management	□
g)	Energy Conservation	□
h)	Exercise	□
i)	Smoking cessation	□
j)	Environmental Health	□
k)	Support services	□
l)	Other (Please list below)	□

……
……
……

13. Who deliver(s) the educational component of your programme?
    Please tick as many options that are applicable

a)	Physiotherapist	□
b)	Exercise Physiologist	□
c)	Nurse	□
d)	Pharmacist	□
e)	Doctor	□
f)	Dietician	□
g)	Occupational Therapist	□
h)	Psychologist	□
i)	Other (Please list below)	□

.....
.....
.....

14. Do you give your patients disease specific education material to take away with them? If respondent answers no, please move to question 16

    Yes □ No □

15. If yes, what are they and in what format are they?
    Please tick as many options that are applicable

a)	Written	□
b)	Audio	□
c)	Visual	□
d)	Other (please list below)	□

……
……
……

16. Do you assess patients' knowledge of their condition? If respondent answers no, please move to question 18

    Yes □ No □

17. If yes, what tool or tools do you currently use to do so?
    Please tick as many options that are applicable
    a) Patient feedback (informal) □
    b) Saint Georges Respiratory Questionnaire (SGRQ) □
    c) Lung Information Needs Questionnaire (LINQ) □
    d) Bristol COPD Knowledge Questionnaire (BCKQ) □
    e) Other/Combinations of others (Please list below) □
    ……
    ……

18. Do you re-assess this on completion of your programme?

    Yes □ No □

19. Do you routinely follow up patients following completion of pulmonary rehabilitation? If respondent answers no, the questionnaire is completed

    Yes □ No □

20. If yes, what does your follow up comprise?
    Please tick as many options that are applicable
    a) Telephone follow up □
    b) Face-to-face informal follow up □
    c) Formal reassessment of all parameters assessed previously □
    d) Other (Please list below) □
    ……

21. At what time points do you carry out your follow ups?
    Please tick as many options that are applicable
    a) On completing the programme □
    b) 1 month after completing the programme □
    c) 2 months after completing the programme □
    d) 3 months after completing the programme □
    e) 6 months after completing the programme □
    f) 12 months after completing the programme □
    g) 18 months after completing the programme □
    h) 24 months after completing the programme □
    i) Other (Please list below) □
    ……
    ……
    ……

Thank you for taking the time to answer this questionnaire.

Appendix 11 - Pilot Cover E-Mail

Principal Investigator: Joy Gana-Inatimi

Dear Sir/Madam

Re: Pilot Pulmonary Rehabilitation Services Survey

Thank you for taking the time to talk to me earlier on today and for expressing interest in taking part in this survey. Following our telephone conversation, as promised I am forwarding you further information about the survey you are considering taking part in.

As I informed you on the phone, my name is Joy Gana-Inatimi and I am a physiotherapist working in pulmonary rehabilitation. I am currently in the process of studying for a PhD at the University of Central Lancashire. As part of my PhD, I will be carrying out research into the impact of self-management education as part of pulmonary rehabilitation on outcomes for patients with COPD. I am conducting a survey of pulmonary rehabilitation services in the North West of England to identify what educational components are included in their programmes and how outcomes are measured.

I have designed a questionnaire to use to interview clinical leads for pulmonary rehabilitation services to collect this information and I would be grateful for your help with this. The interview would involve a short 10 to 15 minute telephone call when I would go through the questions with you and take notes on your responses to each question. For the first few services I am contacting, I am testing out how best to contact people and making sure the questionnaire covers all areas. If it works out ok, I will not need to contact you again, but if there any problems, I may contact you one more time.

All information collected as part of this study will be kept confidential. I attach more information about the study to this email and a copy of the questionnaire for you to look at.

If you are willing to take part in the pilot study, I would be grateful if you could e-mail back to let me know. Once I know that you are willing to take part, I will contact you again to arrange a date/time for a telephone call that is convenient for you.
Thank you for your time. Please do not hesitate to contact me if you have any queries or require further information.

Kind regards

Joy Gana-Inatimi
PhD student and Clinical Lead Physiotherapist for Chest Medicine and Pulmonary Rehabilitation (LHCH)

Contact number: 0151 600 1950
Contact email: JGana-inatimi@uclan.ac.uk

Appendix 12 - Pilot Study Participant Information Sheet

SCHOOL HEADED PAPER

Study Number:……..
Principal Investigator: Joy Gana-Inatimi

Pilot Study Participant Information Sheet

You are being invited to take part in a University of Central Lancashire PhD research study into the impact of self-management education as part of pulmonary rehabilitation on outcomes for patients with COPD. As part of the study, a survey of the different outcome measures and education programmes used as part of pulmonary rehabilitation will be carried out across the North West of England.

What is the purpose of the study and why have I been chosen??
The aim of this study is to investigate the impact of disease specific patient education on recorded patient outcome measures and how they help patients manage their condition better over time. You have been contacted because you have been identified as running a pulmonary rehabilitation programme in the North West of England.

What will happen?
If you agree to participate in the study, the principal investigator will arrange a telephone appointment date and time that is convenient for you to carry out a simple telephone exercise.

What will I be asked to do, if I take part?
If you agree to participate in the study, the principal investigator will arrange a telephone appointment date and time that is convenient for you, in which to carry out the survey using a simple questionnaire. The telephone survey should also take approximately 10-15 minutes to complete with the principal investigator. The questionnaire includes questions regarding the format of your pulmonary rehabilitation programme, what outcome measures are used to assess patients attending your programme and if these are re-evaluated at any other stage(s) during the rehabilitation process. I have included a copy of the questionnaire so that you can see what questions are included. For the first few services I am contacting, I am testing out how best to contact people and making sure the questionnaire covers all areas. If it works out ok, I will not need to contact you again, but if there any changes, I may contact you one more time.

What if there is a problem?
If you have a concern about any aspect of this study, you should first contact the principal investigator (Joy Gana-Inatimi via e-mail at JGana-inatimi@uclan.ac.uk and by telephone on 0151 600 1950). If you have any remaining concerns, please contact the PhD Director of studies (Professor Paola Dey via email at MPDey@uclan.ac.uk and by telephone on 01772 892782).

Will my taking part in this study be kept confidential?
If you decide to take part, all information that is collected about you during the course of the study will be kept strictly confidential and will remain confidential within the study team. You/your organisation will not be able to be identified from any report that is published from this study. We will give each organisation a unique code and once we have collected data from all the trusts we will destroy the key to this code and your responses will be anonymised so that you or your organisation cannot be identified. Therefore, your responses will be anonymised so that you or your organisation cannot be identified from the data collected as part of this study

What if I want to withdraw from the study?
You are free to withdraw from the study. However once we have collected data from all the trusts we will destroy the information that would help us identify the information about your trust. After this time, we would not be able to remove the information that you provide and it will be included in analyses.

What will happen to the results at the end of the research study?
The results of this study will not be known until sometime after the last organisation taking part in the study has completed their questionnaire as part of the survey and the PhD programme of studies has been completed. The data collected will be used to develop a profile of the different pulmonary rehabilitation services available in the North West of England. The findings will be reported in academic and professional publications or presented at academic or clinical meetings but organisations that have participated in the study will not be identified by name. As a participant, and contributor to the study, you will be sent a copy of the summary of the findings of the study. All the information about your participation in this study will be kept confidential and will be stored for 5 years in a locked cabinet and on a password protected and anonymised database following the completion of the study. At the end of 5 years, the data will be destroyed.

Who is organising and funding the research?
The study is being carried out as part of a PhD studentship project with the University of Central Lancashire and is funded by the North West Strategic Health Authority.

Who has reviewed the study?
The study has been reviewed by the Liverpool Heart and Chest Hospital Research Committee, the allocated supervisory team for the PhD project and the University of Central Lancashire's Ethics Committee.

What do I do now?
Thank you for considering taking part in this study. If you have decided to participate in the study, please e-mail the principal investigator at JGana-inatimi@uclan.ac.uk and you will be contacted by the principal investigator to arrange a telephone appointment with you. Please keep this information sheet for your records so that you can contact the principal investigator (Joy Gana-Inatimi via e-mail at JGana-inatimi@uclan.ac.uk and by telephone on 0151 600 1950) or the PhD Director of studies (Professor Paola Dey via email at MPDey@uclan.ac.uk and by telephone on 01772 892782) if you have any queries or require further information. If you decide not to participate, thank you for taking the time to read the information I have sent to you. Please let the principal investigator know via e-mail of your decision, so that you are not contacted again regarding the study.

Contact details:

Principal Investigator:
Name: Joy Gana-Inatimi
Address: PhD Student
Postgraduate School of Medical and Dental Education
University of Central Lancashire
Preston, PR1 2HE
E-mail: JGana-Inatimi@uclan.ac.uk
Telephone: 0151 600 1950

Director of Studies:
Name: Professor Paola Dey
Address: Professor of Public Health Epidemiology
Postgraduate School of Medical and Dental Education
University of Central Lancashire
Preston, PR1 2HE
E-mail: MPDey@uclan.ac.uk
Telephone: 01772 892782

Appendix 13 - Survey Cover E-Mail

Study Number:……..
Principal Investigator: Joy Gana-Inatimi

Dear Sir/Madam

Re: Pulmonary Rehabilitation Services Survey

Thank you for taking the time to talk to me earlier on today and for expressing interest in taking part in this survey. Following our telephone conversation, as promised I am forwarding you further information about the survey you are considering taking part in.

As I informed you on the phone, my name is Joy Gana-Inatimi and I am a physiotherapist working in pulmonary rehabilitation. I am currently in the process of studying for a PhD at the University of Central Lancashire.
As part of my PhD, I will be carrying out research into the impact of self-management education as part of pulmonary rehabilitation on outcomes for patients with COPD. I am conducting a telephone survey of pulmonary rehabilitation services in the North West of England to identify what educational components are included in their programmes and how outcomes are measured.
I have designed a questionnaire to use to interview clinical leads for pulmonary rehabilitation services to collect this information and I would be grateful for your help with this. The interview would involve a short 10 to 15 minute telephone call when I would go through the questions with you and take notes on your responses to each question.
All information collected as part of this study will be anonymised and will be kept confidential. I attach more information about the study to this email and a copy of the questionnaire for you to look at.

If you are willing to take part in the study, I would be grateful if you could e-mail back to let me know. Once I know that you are willing to take part, I will contact you again to arrange a date/time for a telephone call that is convenient for you.
Thank you for your time. Please do not hesitate to contact me if you have any queries or require further information.

Kind regards

Joy Gana-Inatimi
PhD student and Clinical Lead Physiotherapist for Chest Medicine and Pulmonary Rehabilitation (LHCH)

Contact number: 0151 600 1950
Contact email: JGana-inatimi@uclan.ac.uk

Appendix 14 - Survey Study Participant Information Sheet

SCHOOL HEADED PAPER

Study Number:……..
Principal Investigator: Joy Gana-Inatimi

Survey Study Participant Information Sheet

You are being invited to take part in a University of Central Lancashire PhD research study into the impact of self-management education as part of pulmonary rehabilitation on outcomes for patients with COPD. As part of the study, a survey of the different outcome measures and education programmes used as part of pulmonary rehabilitation will be carried out across the North West of England.

What is the purpose of the study and why have I been chosen??
The aim of this study is to investigate the impact of disease specific patient education on recorded patient outcome measures and how they help patients manage their condition better over time. You have been contacted because you have been identified as running a pulmonary rehabilitation programme in the North West of England.

What will happen?
If you agree to participate in the study, the principal investigator will arrange a telephone appointment date and time that is convenient for you to carry out a simple telephone exercise.

What will I be asked to do, if I take part?
If you agree to participate in the study, the principal investigator will arrange a telephone appointment date and time that is convenient for you, in which to carry out the survey using a simple questionnaire. The telephone survey should also take approximately 10-15 minutes to complete with the principal investigator. The questionnaire includes questions regarding the format of your pulmonary rehabilitation programme, what outcome measures are used to assess patients attending your programme and if these are re-evaluated at any other stage(s) during the rehabilitation process. I have included a copy of the questionnaire so that you can see what questions are included.

What if there is a problem?
If you have a concern about any aspect of this study, you should first contact the principal investigator (Joy Gana-Inatimi via e-mail at JGana-inatimi@uclan.ac.uk and by telephone on 0151 600 1950). If you have any remaining concerns, please contact the PhD Director of studies (Professor Paola Dey via email at MPDey@uclan.ac.uk and by telephone on 01772 892782).

Will my taking part in this study be kept confidential?
If you decide to take part, all information that is collected about you during the course of the study will be kept strictly confidential and will remain confidential within the study team. You/your organisation will not be able to be identified from any report that is published from this study. We will give each organisation a unique code and once we have collected data from all the trusts we will destroy the key to this code and your responses will be anonymised so that you or your organisation cannot be identified. Therefore, your responses will be anonymised so that you or your organisation cannot be identified from the data collected as part of this study

What if I want to withdraw from the study?
You are free to withdraw from the study. However once we have collected data from all the trusts we will destroy the information that would help us identify the information about your trust. After this time, we would not be able to remove the information that you provide and it will be included in analyses.

What will happen to the results at the end of the research study?
The results of this study will not be known until sometime after the last organisation taking part in the study has completed their questionnaire as part of the survey and the PhD programme of studies has been completed. . The data collected will be used to develop a profile of the different pulmonary rehabilitation services available in the North West of England. The findings will be reported in academic and professional publications or presented at academic or clinical meetings but organisations that have participated in the study will not be identified by name. As a participant, and contributor to the study, you will be sent a copy of the summary of the findings of the study. All the information about your participation in this study will be kept confidential and will be stored for 5 years in a locked cabinet and on a password protected and anonymised database following the completion of the study. At the end of 5 years, the data will be destroyed.

Who is organising and funding the research?
The study is being carried out as part of a PhD studentship project with the University of Central Lancashire and is funded by the North West Strategic Health Authority.

Who has reviewed the study?
The study has been reviewed by the Liverpool Heart and Chest Hospital Research Committee, the allocated supervisory team for the PhD project and the University of Central Lancashire's Ethics Committee.

What do I do now?
Thank you for considering taking part in this study. If you have decided to participate in the study, please e-mail the principal investigator at JGana-inatimi@uclan.ac.uk and you will be contacted by the principal investigator to arrange a telephone appointment with you. Please keep this information sheet for your records so that you can contact the principal investigator (Joy Gana-Inatimi via e-mail at JGana-inatimi@uclan.ac.uk and by telephone on 0151 600 1950) or the PhD Director of studies (Professor Paola Dey via email at MPDey@uclan.ac.uk and by telephone on 01772 892782) if you have any queries or require further information. If you decide not to participate, thank you for taking the time to read the information I have sent to you. Please let the principal investigator know via e-mail of your decision, so that you are not contacted again regarding the study.

Contact details:

Principal Investigator:
Name: Joy Gana-Inatimi
Address: PhD Student
Postgraduate School of Medical and Dental Education
University of Central Lancashire
Preston, PR1 2HE
E-mail: JGana-Inatimi@uclan.ac.uk
Telephone: 0151 600 1950

Director of Studies:
Name: Professor Paola Dey
Address: Professor of Public Health Epidemiology
Postgraduate School of Medical and Dental Education
University of Central Lancashire
Preston, PR1 2HE
E-mail: MPDey@uclan.ac.uk
Telephone: 01772 892782

Appendix 15 - Pulmonary Rehabilitation Service Survey Study Questionnaire

SCHOOL HEADED PAPER
Study Number:……..
Principal Investigator: Joy Gana-Inatimi

Pulmonary Rehabilitation Service Survey Study Questionnaire

Thank you for your help with this questionnaire. I will be phoning you soon to go through the questions. The purpose of this questionnaire is to gather information regarding the provision of pulmonary intervention for patients with COPD patients across the North West of England. Your responses will be used to create a description of the availability and distribution of pulmonary rehabilitation service based in the North West as part of a University of Central Lancashire PhD project investigating the impact of pulmonary rehabilitation intervention on COPD patients.
You may wish to spend some time going through the questions in preparation for my telephone call. If after reading the questionnaire, you no longer wish to take part, please contact me by email

1. In what type of NHS organisation is the pulmonary rehabilitation service based?
   Please tick only one option
   a) Primary Care □
   b) Secondary Care □
   c) Tertiary Care □
   d) Other □
   If other, please tell me what type of organisation .....

2. What groups of health professionals are involved in the day to day delivery of your programme?
   Please tick as many options that are applicable
   a) Physiotherapist □
   b) Exercise Physiologist □
   c) Nurse □
   d) Pharmacist □
   e) Doctor □
   f) Dietician □
   g) Occupational Therapist □
   h) Psychologist □
   i) Other (Please list below) □

.....
.....

3. What type of pulmonary rehabilitation service do you provide?
   Please tick only one option
   a) Hospital based service □
   b) Community based service □
   c) Both Hospital and community based services □

4. Do you provide a service for COPD patients on oxygen?

Yes □ No □

5. How long is your programme, i.e., number of weeks?
   Please tick only one option
   a) 1 week □
   b) 2 weeks □
   c) 3 weeks □
   d) 4 weeks □
   e) 5 weeks □
   f) 6 weeks □
   g) 7 weeks □
   h) 8 weeks □
   i) 9 weeks □
   j) 10 weeks □
   k) 11 weeks □
   l) 12 weeks □
   m) Other (Please list below) □

……

6. How often do patients have to attend the sessions?
   Please tick only one option
   a) Once a week □
   b) Twice a week □
   c) Other (Please list below) □

……

7. What does your pulmonary rehabilitation programme comprise?
   Please tick only one option
   a) Exercise only □
   b) Education only □
   c) Both Exercise and Education □
   d) Other (Please list below) □

8. Do you provide any home exercises for your patients? If respondent answers no, please go to question 11

   Yes □ No □

9. If yes, what do you provide?
   Please tick only one option
   a) Exercise routine □
   b) Exercise routine and equipment □
   c) Other (Please list below) □

……

10. How often do you advise patients to carry out their home exercise programme (min frequency)?
    Please tick only one option
    a) Once a week □
    b) Twice a week □
    c) Three times a week □
    d) Alternate days □
    e) Daily □
    f) Other (Please list below) □

……

11. Do you have a formal or structured education component to your pulmonary rehabilitation programme? If respondent answers no, please go to question 14

Yes □ No □

12. If yes – what topics do you cover?
    Please tick as many options that are applicable

a) Disease education □
b) Medication □
c) Symptom management □
d) Diet □
e) Stress management □
f) Anxiety management □
g) Energy Conservation □
h) Exercise □
i) Smoking cessation □
j) Environmental Health □
k) Support services □
l) Other (Please list below) □

……
……
……

13. Who deliver(s) the educational component of your programme?
    Please tick as many options that are applicable

a) Physiotherapist □
b) Exercise Physiologist □
c) Nurse □
d) Pharmacist □
e) Doctor □
f) Dietician □
g) Occupational Therapist □
h) Psychologist □
i) Other (Please list below) □

.....
.....
.....

14. Do you give your patients disease specific education material to take away with them? If respondent answers no, please go to question 16

    Yes □ No □

15. If yes, what are they and in what format are they?
    Please tick as many options that are applicable

a) Written □
b) Audio □
c) Visual □
d) Other (please list below) □

……
……
……

16. Do you assess patients' knowledge of their condition? If respondent answers no, please go to question 18

    Yes □ No □

17. If yes, what tool or tools do you currently use to do so?
    Please tick as many options that are applicable
a) Patient feedback (informal) □
b) Saint Georges Respiratory Questionnaire (SGRQ) □
c) Lung Information Needs Questionnaire (LINQ) □
d) Bristol COPD Knowledge Questionnaire (BCKQ) □
e) Other/Combinations of others (Please list below) □

……
……

18. Do you re-assess this on completion of your programme?

Yes □ No □

19. Do you routinely follow up patients following completion of pulmonary rehabilitation? If respondent answers no, this is the end of the questionnaire

Yes □ No □

20. If yes, what does your follow up comprise?
    Please tick as many options that are applicable
    a) Telephone follow up □
    b) Face-to-face informal follow up □
    c) Formal reassessment of all parameters assessed previously □
    d) Other (Please list below) □

    ……

21. At what time points do you carry out your follow ups?
    Please tick as many options that are applicable
    a) On completing the programme □
    b) 1 month after completing the programme □
    c) 2 months after completing the programme □
    d) 3 months after completing the programme □
    e) 6 months after completing the programme □
    f) 12 months after completing the programme □
    g) 18 months after completing the programme □
    h) 24 months after completing the programme □
    i) Other (Please list below) □

    ……
    ……
    ……

Thank you for taking the time to answer this questionnaire.

Appendix 16 – Liverpool Heart and Chest Hospital Trust Permission Letter

Liverpool Heart and Chest Hospital NHS
NHS Foundation Trust

Date: 17/01/11

PRIVATE AND CONFIDENTIAL

Professor MP Dey
Professor of Public Health Epidemiology
University of Central Lancashire

Dear Professor Dey

Re: PhD Studentship for Mrs Joy Gana-Inatimi

As Research manager for the Trust, I can confirm that the Liverpool Heart and Chest Hospital NHS Foundation Trust fully support Mrs Joy Gana-Inatimi in her PhD study. This support includes access to the following areas relating to her programme of study:

- Full permission to extract data from the pulmonary rehabilitation database
- Permission to carry out retrospective analysis of anonymised data from the pulmonary rehabilitation
- No additional permission from the Trust Caldecott guardian is required for Mrs Gana-Inatimi to access the database for the purpose of the analysis of the retrospective data
- Permission that anonymised data can be stored separately for the purpose of this study and can be accessed by the supervisory team from UCLan
- Full access to patients attending the pulmonary rehabilitation programme for the purpose of recruitment and assessment as part of the prospective phase of the programme of study
- Permission to use the data from the programme of studies for the purpose of presentations, conferences, etc as part of the PhD programme of studies

Please do not hesitate to contact me if you require further information regarding this matter.

Yours sincerely

Dr Margarita Perez-Casal
Research, Audit and Effectiveness Manager
Department of Clinical Quality

Appendix 17 - Liverpool Heart and Chest Hospital Trust Data Access Permission

Liverpool Heart and Chest Hospital NHS
NHS Foundation Trust

Thomas Drive
Liverpool
L14 3PE

Department of Clinical Quality
0151 600 1370
0151 288 2371

Professor M Paola Dey
Professor of Public Health
Epidemiology
University of Central Lancashire

20th December 2010

Dear Professor Dey,

On behalf of the Liverpool Heart & Chest NHS Foundation Trust Research and Development Department, I can confirm that Mrs Joy Gana-Inatimi has been allowed full access to the Pulmonary Rehabilitation Database for the purpose of the research project on her PhD study.

Yours sincerely,

Dr Margarita Perez-Casal
Research & Audit Manager

Appendix 18 – Ethics Clarification Email

From: Perez-Casal Margarita
Sent: Monday 21 March 2011 11:15
To: Gana Joy
Subject: RE: FHEC application form

It depends or whether you are collecting any additional data to that already collected by routine. If you are not, and the study is retrospective, you don't need ethics. But, if you are collecting new data, even if they're anonimised, you would require ethics.
Is that more or less clear?...

Dr Margarita Perez-Casal
Research, Audit and Effectiveness Manager
Department of Clinical Quality
Liverpool Heart and Chest Hospital NHS Foundation Trust
Thomas Drive
Liverpool L14 3PE

E-mail: Margarita.Perez-Casal@lhch.nhs.uk
Direct line: 0151 6001467
Secretary: 0151 6001370

From: Gana Joy
Sent: Monday 21 March 2011 10:39
To: Perez-Casal Margarita
Subject: FW: FHEC application form

Hi Marga
How are you? It was lovely to see you the other day after such a long time. I've come knocking again at your door with a query from Prof Dey. Do I need NRes approval for the database study which will be using anonymised data from PR patients?
Many thanks.

Kind Regards,

Joy

Joy Gana-Inatimi
Clinical Lead Chest Medicine, Pulmonary Rehabilitation and Training/Education
The Liverpool Heart and Chest Hospital NHS Foundation Trust

☎ 0151 228 1616 Bleep 2160
Fax. No. 0151 600 1659
joy.gana@lhch.nhs.uk

Visit our website on www.lhch.nhs.uk

Appendix 19 – UCLAN Ethics Approval (Retrospective Study)

22nd June 2011

Paola Dey/Joy Gana-Inatimi/Chris Sutton/H Stewart
Postgraduate School of Medical and Dental Education
University of Central Lancashire

Dear Paola, Joy & Chris

Re: Faculty of Health & Social Care Ethics Committee (FHEC) Application - (Proposal No.503)

The FHEC has granted approval of your proposal application 'The impact of Pulmonary rehabilitation self-management education on outcomes in patients with COPD – Pulmonary rehabilitation services study' on the basis described in its 'Notes for Applicants'.

We shall e-mail you a copy of the end-of-project report form to complete within a month of the anticipated date of project completion you specified on your application form. This should be completed, within 3 months, to complete the ethics governance procedures or, alternatively, an amended end-of-project date forwarded to Research Office.

Yours sincerely

Miltos Ladikas
Deputy Vice Chair
Faculty of Health Ethics Committee

Appendix 20 – Literature Review Data Form

Study Design			Study Population				Study Outcome	
Author(s)	**Year of Publication**	**Type of Study**	**Condition**	**Country and Setting**	**Number of Participants**	**Characteristics of Participants**	**Study Details**	**Study Results**
Siddique HH Olson RH Parenti CM Rector TS Caldwell M Dewan NA Rice KL Randomised trial of pragmatic education for low risk COPD patients: impact on hospitalisations and emergency department visits International Journal of COPD 2012:7 719 - 728	2012	RCT	**COPD**	USA (Primary care)	4425	**Age:** None stated **Disease Severity:** None stated but classified as low risk COPD patients **Eligibility Criteria:** 1. Clinical diagnosis of COPD – spirometry confirmed 2. FEV1/FVC ratio of <70% and FEV1 < 80%	**Intervention:** CG had usual care and the IG received a locally developed COPD education brochure. After 3 months the IG also received a second brochure containing a review of the information in the first brochure and patient testimonials about the benefits of adhering to evidence based COPD treatment. **Outcome measure(s):** 1. Number of hospital admissions and ED visits within the VA 2. Number of self-reported breathing-related hospital admissions in non-VA facilities 3. All-cause mortality 4. COPD knowledge **Length of follow up:** 12 months	Rates of COPD related admissions in VA facilities did not differ between the groups (*P*=0.77). Self-reported hospitalisations for breathing-related problems in non-VA facilities were lower in the IG (*P*=0.006) indicating that a practical educational intervention incorporating principles of chronic disease management may reduce the rate of breathing related hospitalisations in the large proportion of patients with COPD who are at relatively low-risk for such events. **Limitations/weaknesses/comments:** 1. No clear criteria re: classification for high or low risk patients or how this was decided and by whom 2. No definition of usual care and what it entailed 3. 162 deaths in CG and 141 in IG

Study Design			Study Population				Study Outcome	
Author(s)	**Year of Publication**	**Type of Study**	**Condition**	**Country and Setting**	**Number of Participants**	**Characteristics of Participants**	**Study Details**	**Study Results**
Fan VS Gaziano MJ Lew R Bourbeau J Adams SG Leatherman S Thwin SS Huang GD Robbins R Sriram PS Sharafkhaneh A Mador MJ Sarosi G Panos RJ Rastogi P Wagner TH Mazzuca SA Shannon C Colling C Liang MH Stoller JK Fiore L Niewoehner DE A Comprehensive Care Management Program to Prevent Chronic Obstructive Pulmonary Disease Hospitilisations *Ann Intern Med.* 2012; 156:673-683	2012	RCT	**COPD**	USA (Primary care)	426 217 (CG) 209 (IG)	**Age:** Older than 40 years **Disease Severity:** None stated **Eligibility Criteria:** 1. Hospitalised for COPD in the 12 months before enrolment 2. Postbronchodilator FEV1/FVC below 0.7 with an FEV1 < 80% predicted 3. Current or past history of cigarette smoking (> 10 pack - years) 4. At least 1 visit in the past year to either a primary care or pulmonary clinic at a Veterans Affairs (VA) medical centre 5. No COPD exacerbation in the past 4 weeks 6. Ability to speak English 7. Access to a telephone	**Intervention:** CG – usual care as per the Global Initiative (GOLD) for Chronic Obstructive Lung Disease guidelines. IG – Comprehensive Care Management Programme (CCMP) included COPD education during 4 individual sessions and 1 group session, an action plan for identification and treatment of exacerbations, and scheduled proactive telephone calls for case management. Both groups received COPD information booklet. Their primary care providers received a copy of GOLD COPD guidelines and were advised to manage these patients according to these guidelines. **Outcome measure(s):** 1. Time to first COPD hospitalisation 2. Non-COPD health care use 3. All-cause mortality 4. Health Related Quality of Life (HRQoL) 5. Patient satisfaction 6. Disease knowledge 7. Self-efficacy **Length of follow up:** 1 year	The incidence of COPD related hospitalisations was 27% in the IG and 24% in the CG. During the first 12 months, 600 self-reported COPD exacerbations occurred in the IG (mean 4.4 per patient-year) and 610 in the CG (mean, 4.3 per patient-year). An average of 2.5 exacerbations per patient-year were treated with prednisolone in the IG compared with 2.1 in the CG (*P*=0.011). When the study was terminated, 28 patients in the IG and 10 in the CG had died (*P*=0.003). at the six-month follow-up, 11 deaths (3 due to COPD) had occurred in the IG and 15 in the IG (4 due to COPD). This study was unable to show that a theory based CCMP reduced COPD related hospitalisations. The study was stopped because the all-cause mortality was higher in the IG. The study could not demonstrate an improvement in COPD knowledge but there was a modest statistically significant difference in the rate of use of prednisolone per exacerbation but not antibiotics and the differences in the timings of either prednisolone or antibiotic use were not statistically significant.

								Limitations/weaknesses/comments: 1. 20 centres 2. Excess mortality in the IG – data unable to explain this phenomenon 3. Citing serious safety concerns, the data monitoring committee terminated the intervention before the trial's planned completion

Study Design			Study Population				Study Outcome	
Author(s)	**Year of Publication**	**Type of Study**	**Condition**	**Country and Setting**	**Number of Participants**	**Characteristics of Participants**	**Study Details**	**Study Results**
Trappenburg JCA Monninkhof EM Bourbeau J Troosters T Schrijvers AJP Verheij TJM Lammers JWJ Effect of an action plan with ongoing support by a case manager outcome in patients with COPD: a multicentre randomised controlled trial *Thorax* 2011; **66:977** - 984	2011	RCT	**COPD**	Netherlands (Primary and Secondary care)	233 111 (IG) 122 (CG)	**Age:** **Disease Severity:** **Eligibility Criteria:** 1. Post bronchodilator FEV1/FVC < 70% 2. Smoking history > 20years or 15 pack years 3. Diagnosis of COPD as a major functionally limiting disease 4. Current use of bronchodilator therapy	**Intervention:** Patients in both arms received usual care which included pharmacological and non-pharmacological care according to evidence based guidelines. At the inclusion stage, all patients were seen by the nurse case manager who discussed vaccination, optimising medication, inhaler techniques, exercise, nutritional aspects, smoking cessation and exacerbation management. The action plan for the IG was individualised by the nurse case manager **Outcome measure(s):** 1. Health Related Quality of Life (HRQoL) – St Georges Respiratory Questionnaire (SGRQ) 2. Anxiety and depression (Hospital Anxiety and Depression Scale) 3. Exacerbation related self-efficacy 4. Clinical COPD Questionnaire (CCQ) **Length of follow up:** 6 months	During the study period 264 symptom-based exacerbations occurred with 128 in the IG and 136 in the CG. Single time point comparisons showed that, in the first 3 days after onset, the mean CCQ total, symptom and functional scores were significantly lower in the IG. Change in health status between baseline and first measurement post onset was associated with health status recovery time ($r=0.68$, $p<0.001$) indicating that exacerbations have a high impact on health status with a longer time to recover. When an exacerbation was reported, the IG reported on average 2.9 days faster than those in the control group ($p<0.001$). No statistical differences were observed in the mean change in SGRQ and HADS scores. **Limitations/weaknesses/comments:** 1. Mixed settings 2. Guidelines not specified – referred to as the most recent evidence based guidelines 3. No data on self-management strategies used or action plans

Study Design			Study Population				Study Outcome	
Author(s)	**Year of Publication**	**Type of Study**	**Condition**	**Country and Setting**	**Number of Participants**	**Characteristics of Participants**	**Study Details**	**Study Results**
Wakabayashi R Motegi T Yamada K Ishii T Jones RCM Hyland ME Gemma A Kida K Efficient integrated education for older patients with chronic obstructive pulmonary disease using the Lung Information Needs Questionnaire *Geriatr Gerontol Int 2011;* **11:422** - 430	2011	RCT	**COPD**	Japan (Secondary care)	102 42 (IG) 43 (CG)	**Age:** > 65 years old **Disease Severity:** None stated **Eligibility Criteria:** 1. Clinical diagnosis of COPD including airflow obstruction assessed by pulmonary function tests with post-bronchodilator inhalation 2. Exclusively visit the clinic 3. History of cigarette smoking (current and former) 4. Exacerbation free for the preceding 3 months 5. Mini Mental State Examination (MMSE) score > 26	**Intervention:** IG received individually tailored programmes according to their domain scores on the Lung Information Needs Questionnaire (LINQ). Treatment and health-care management plans were constructed on the basis of each patient's individual self-management needs. Education based on the LINQ domains was performed in monthly individual sessions for the initial 6 months (intensive education period) with at least 30 minutes spent with each patient. All patients in the IG were provided with a booklet that was used during each session. After the intensive education period, the IG were followed up in the same way as the patients in the CG. **Outcome measure(s):** 1. LINQ score 2. Pulmonary function test 3. Dyspnoea scale – Modified Medical Research Council Dyspnoea Scale (MMRC) 4. Exercise capacity – Six Minute Walk Test (6MWT) 5. Body Mass Index (BMI) 6. Activities of Daily Living (ADL) 7. BODE index 8. Health Status – St George's Respiratory Questionnaire (SGRQ) 9. Comorbidities **Length of follow up:** 12 months	Results showed significant improvement in LINQ scores in the IG at 6 months (P<0.02), including understanding of COPD and avoidance of exacerbations (P<0.01 and P<0.02 respectively). No changes were observed in the CG after 6 months. Smoking cessation and exercise significantly worsened in the CG at the 12-month follow-up (P=0.005 and P<0.0001 respectively). A significant improvement was noted in MMRC at 12 months compared to baseline in the IG (P<0.01), whereas the CG showed a significant worsening at 12 months (P<0.03). BODE index scores in the IG were significantly improved at 12 months compared to baseline (P<0.02), whereas they were significantly worsened in the CG (P<0.03). Instrumental ADL was improved in the IG at 6 months (P<0.03) and remains stable at 12 months. No hospitalisations were noted in the IG during the initial 6 month period (P<0.04), however, there was no significant difference between the groups during the follow-up period. This education strategy improved patient information needs, ADL, dyspnoea and BODE index as well as reducing the number of hospital admissions during the period of integrated education (P=0.033).

								Limitations/weaknesses/comments: 1. Advanced age of the patients 2. Highly motivated patients chosen due to the nature of the referral system for the clinic both groups received COPD booklet that incorporated the LINQ domains

Study Design			Study Population				Study Outcome	
Author(s)	**Year of Publication**	**Type of Study**	**Condition**	**Country and Setting**	**Number of Participants**	**Characteristics of Participants**	**Study Details**	**Study Results**
Sedano MF Nault D Hamd DH Bourbeau J A Self-Management Education Programme Including an Action Plan for Acute COPD Exacerbations *COPD: Journal of Chronic Obstructive Pulmonary Disease*, 6:352-358	2009	RCT	**COPD**	Canada (Primary care)	191	**Age:** Not stated **Disease Severity:** Moderate to severe COPD **Eligibility Criteria:** None stated	**Intervention:** IG received the 7 education modules of the self-management program "Living Well with COPD", including a written action plan with prescription of antibiotic and prednisolone for self-administration in the event of an exacerbation and supervision by case manager. The self-management programme consisted of home teaching 1 hour/week for 7 – 8 weeks, reviewing different self-management topics such as basic COPD information, breathing, relaxation, energy conservation techniques and the use of an action plan during exacerbations. The program was supervised by experienced case managers, in collaboration with treating physicians. In addition during periodically scheduled telephone calls (weekly during the 2-month education period and monthly for the remainder of the study), the case manager reviewed patients' and the use of self-management strategies. Periodic evaluation visits at baseline, 4 and 12 months were carried out. **Outcome measure(s):** 1. Symptom diary 2. Hospital/clinic visits **Length of follow up:** 12 months	Baseline characteristics were similar across sociodemographic, clinical and functional variables, except for smoking history which was higher in the IG (p=0.02). A total of 661 exacerbations were reported during the study period. Fifty-five exacerbations were excluded from analysis. Antibiotics use was reported in 61.6% of all exacerbations, while oral corticosteroids were used in 47.9%. A higher proportion of exacerbations presenting with changes in 2 or more major symptoms were treated with antibiotics and prednisolone in the IG compared to the CG (54.4% vs 34.8%, p <0.001). This difference was also seen in the 203 exacerbations with only 1 symptoms (35.3% vs 17.8%, p=0.005). Moreover in the CG, a greater percentage of exacerbations presenting worsening of 2 or more symptoms were treated only with antibiotics or not treated at all (60.0% vs 38.3%, p<0.001). Earlier initiation of treatment in the IG was more pronounced in the last exacerbation experienced by each patient in the 12-month follow-up period (80.5% vs 59.1%, p=0.068). In exacerbations treated with both antibiotics and prednisolone, comparing the IG to the CG, there was a significantly reduced risk of

								hospitalisation (17.2% vs 36.3%, *p*<0.001), emergency room visits (29.9% vs 54.4%, *p*<0.001) and unscheduled physician visits (8.2% vs 30.9%, *p*<0.001). The self-management programme led to changes in patient behaviour, i.e., more than 50% of patients promptly self-treated their exacerbations with antibiotics and prednisolone. This appropriate adoption of self-management was associated with a reduction in hospital admissions and emergency visits. **Limitations/weaknesses/comments:** 1. Eligibility criteria not stated 2. All patients received action plans and therefore this was not tested separately in the event of an exacerbation 3. 55 out of the 661 reported exacerbations were excluded from analysis 4. Lack of information regarding the failure of some patients in the IG to successfully use antibiotics and prednisolone in the event of an exacerbation 5. Insufficient time frame to effect behavioural change, especially among those who had 1 exacerbation

Study Design			Study Population				Study Outcome	
Author(s)	**Year of Publication**	**Type of Study**	**Condition**	**Country and Setting**	**Number of Participants**	**Characteristics of Participants**	**Study Details**	**Study Results**
Khdour M Kidney JC Smyth BM McElnay JC Clinical pharmacy-led disease and medicine management programme for patients with COPD Br J Clin Pharmacol **68**:4, 588-598	2009	RCT	**COPD**	UK (Secondary care)	173 86 (IG) 87 (CG)	**Age:** > 45 years old **Disease Severity:** None stated **Eligibility Criteria:** 1. Confirmed diagnosis of COPD by the hospital consultant for at least 1 year 2. FEV1 30 – 80% of predicted value	**Intervention:** IG were managed with complex intervention as described by the Medical Research Council. IG patients were educated individually on COPD, their prescribed medication, the importance of adherence, inhaler technique and management of COPD symptoms. **Outcome measure(s):** 1. Hospital admissions 2. Health Related Quality of Life (HRQoL) - St George's respiratory Questionnaire (SGRQ) 3. Spirometry (FEV1) 4. Body Mass Index (BMI) 5. Disease knowledge - COPD knowledge questionnaire 6. Self-reported adherence - Moriskey adherence questionnaire **Length of follow up:** 12 months	Significant reduction in both hospital admissions (*P*=0.01) and ED visits (*P*=0.02) for acute exacerbations of COPD in the IG. Unscheduled visits to the GP were significantly higher in the CG at 6 months and 12 months (*P*=0.01). Significant improvements in the symptoms (*P*=0.01), impact (*P*=0.01) and total (*P*=0.04) subscales of the SGRQ at the 6-month follow-up point in the IG compared to the CG. At the 12-month assessment, the differences between IG and CG in the symptoms (*P*=0.04) and impact (*P*=0.03) subscales remained statistically significant. No difference in FEV1, BMI and stage of change status in relation to smoking between both groups at baseline and 12-month assessment points. At baseline, the number of patients in both groups with low adherence was approximately the same in both groups. At the 6 and 12 month assessment points, a higher proportion of patients in the IG exhibited high adherence scores than the CG (81% vs 63% and 77.8% vs 60%, *P*=0.019). There was no difference in knowledge scores in both groups at baseline but patient knowledge scores were higher in the IG at 6 and 12 months (*P*<0.001). **Limitations/weaknesses/comments:**

								1. As a greater percentage of patients with moderate and severe disease were admitted to hospital, such patients should be targeted for the intervention 2. Timing of intervention 3. Poor levels of smoking intervention

Study Design			Study Population				Study Outcome	
Author(s)	**Year of Publication**	**Type of Study**	**Condition**	**Country and Setting**	**Number of Participants**	**Characteristics of Participants**	**Study Details**	**Study Results**
Efraimsson EO Hillervik C Ehrenberg A Effects of COPD self-care management education at a nurse-led primary health care clinic *Scand J Caring Sci,* 2008; 22; 178 - 185	2008	RCT	**COPD**	Sweden (Primary care)	52	**Age:** **Disease Severity:** Mild, moderate, severe or very severe COPD (GOLD criteria) **Eligibility Criteria:** 1. Diagnosis of COPD 2. No mental health disorders or emotional dysfunction (anxiety or depression)	**Intervention:** Both groups received standard care and the IG group were offered follow-up sessions with a COPD specialist nurse. IG received education with an emphasis of self-care ability and how to support the individual based on their unique requirements and abilities to cope with disease and treatment. The main components of the educational visits were pathophysiology of COPD, spirometry, optimisation of pharmacological treatment including inhaler technique, smoking cessation, dealing with exacerbations, oximetry, breathing and relaxation techniques, physical activity and exercise, counselling on infection prevention and individual treatment plans. **Outcome measure(s):** 1. Health Related Quality of Life (HRQoL) - St George's respiratory Questionnaire (SGRQ) 2. Smoking 3. Knowledge about COPD **Length of follow up:** 3-5 months	Significant reduction in patient's symptoms in the IG (p=0.00035). No change was observed in the CG. Increase in activities that reduced their dyspnoea was observed in the IG but none reported in the CG (p=0.0267). Significant reduction in the impact of COPD on psycho-social health was also observed in the IG and no change in the CG (p=0.0161). HRQoL was improved in the IG with no change observed in the CG (p=0.00030). In the IG 37.5% of patients who were smokers had stopped smoking during the intervention phase but none of the smokers in the CG stopped smoking (p=0.0185). At baseline, there was no difference between the groups regarding knowledge of COPD but there was a significant difference post-intervention (p<0.001). **Limitations/weaknesses/comments:** 1. One of the researchers was also a nurse that provided the intervention, introducing a potential conflict of interest and introducing a potential source of responder bias 2. Potential of selection bias due to the close working relationship between the nurses, one of whom was a researcher and the physicians 3. Relatively small sample 4. Unclear follow-up protocol including follow-up time

Study Design			Study Population				Study Outcome	
Author(s)	**Year of Publication**	**Type of Study**	**Condition**	**Country and Setting**	**Number of Participants**	**Characteristics of Participants**	**Study Details**	**Study Results**
McGeoch GRB Willsman KJ Dowson CA Town GI Frampton CM McCartin FJ Cook JM Epton MJ *Respirology* (2006) **11**, 611 - 618	2006	RCT	**COPD**	New Zealand (Primary care)	159	**Age:** Onset age > 35 years old **Disease Severity:** None stated **Eligibility Criteria:** 1. Diagnosed with COPD according to the American Thoracic Society criteria (history of cough, sputum, shortness of breath with a background of tobacco smoking > 10 pack-years) 2. FEV1/FV <70% (spirometry within 12 months) 3. Symptoms at lease weekly 4. History of 1 or more exacerbations in the previous 12 months requiring an increase in therapy	**Intervention:** IG received usual care and education on the use of a self-management plan (action plan). The plan and structured education included methods of early recognition of exacerbations and range of appropriate self-initiated interventions including antibiotics and short-course oral corticosteroids. In addition, patients were instructed to make early contact with their general practice during exacerbations. Standardised self-management education was delivered in an individual session of 1 hour duration from a practice nurse or respiratory educator in association with their general practitioner. The CG received usual care from their general practice team and were specifically denied access to the written self-management plan. Non standardised education was provided on smoking cessation, exercise, controlling breathlessness, nutrition, use of inhaled therapy and immunisation according to individual practice standards. **Outcome measure(s):** 1. Health Related Quality of Life (HRQoL) - St George's respiratory 2. Health utilisation (frequency of hospital and primary care attendance and frequency of use of courses of antibiotics and oral corticosteroids) 3. Emotional functioning – Hospital Anxiety and Depression Scale (HADS) 4. Disease knowledge - COPD Self-Management Interview (COPD-SMI) **Length of follow up:** 12 months	Both groups were similar at baseline except for the IG had higher SGRQ scores which were statistical significance for symptom and impact domains and the total score. No statistically significant differences were shown between the groups for improvement in quality of life (SGRQ), health utilisation or anxiety and depression (HADS). There was no correlation in either group between initial level of any outcome measured and subsequent change. At 12 months, higher COPD-SMI scores were observed in the IG for SMI well knowledge (p=0.001), SMI early exacerbation knowledge (P=0.001), SMI early exacerbation actions (P=0.001), SMI severe exacerbation knowledge (P=0.002) and SMI severe exacerbation actions (P=0.005). **Limitations/weaknesses/comments:** 1. Unblinded – therefore potential of selection bias 2. Randomisation by practice rather than individuals

Study Design			Study Population				Study Outcome	
Author(s)	**Year of Publication**	**Type of Study**	**Condition**	**Country and Setting**	**Number of Participants**	**Characteristics of Participants**	**Study Details**	**Study Results**
Bourbeau J Collet JP Schwartzman K Bradley C Economic Benefits of Self-Management Education in COPD Chest 2006; 130: 1704-1711	2006	RCT	**COPD**	Canada (Secondary care)	191	**Age:** > 50 years old **Disease Severity:** Moderate - severe airflow obstruction **Eligibility Criteria:** 1. Post bronchodilator FEV1 between 25% and 70% of the predicted value 2. FEV1/FVC ratio < 70% 3. Smoking history of at least 10 pack-year 4. History of hospitalisation for at least one exacerbation in the preceding year	**Intervention:** The IG received standardised education on the COPD self-management programme as well as ongoing supervision by a case manager. The patient education included skill-oriented teaching at home for 6 to 7 weeks, depending if the patient needed home oxygen and agreed to perform the home exercise program. Monthly follow-up telephone calls were made after the end of all teaching sessions. Patients in the IG could reach the case manager during work hours via a pager or a dedicated telephone line. The teaching material included a flipchart designed for health educators and seven skill-oriented patient workbooks covering the following topics: 1. Basic information about COPD, breathing and coughing techniques, energy conservation during day-to-day activities and relaxation exercises 2. Preventing and controlling symptoms through inhalation techniques 3. Understanding and using a plan of action for acute exacerbation 4. Adopting a healthy lifestyle (smoking cessation, nutrition, sleep habits, sexuality, managing emotion) 5. Leisure activities and travelling 6. A simple home exercise program, not supervised, except for an initiation visit 7. Long-term oxygen therapy when appropriate An audiotape was given to every patient to be used at home in order to assist with the implementation of relation techniques such as deep breathing, progressive muscular relaxation and visualisation. The written action plan for exacerbations included a list of contact persons and a symptom monitoring list tailored to specific precipitants (stress, environmental changes, respiratory tract infections). The symptom list was linked with appropriate	Baseline characteristics of the two groups were similar with respect to sociodemographic variables, disease severity and previous use of health services. During the 1 year follow-up, the frequency of hospital admission was significantly lower in the self-management group than in the usual care group, as were hospital days per patient, emergency department visits and unscheduled physician visits. The mean healthcare cost per patient was $3,338 lower for the IG than the CG (p=0.024). **Limitations/weaknesses/comments:** 1. Not possible to blind participants in this study 2. No evaluation of the interactions with the case manager

							therapeutic actions, including prescription of antibiotics and oral corticosteroids to be kept at home and used in the event of an exacerbation. To promote exercise at home, a stationary bicycle was provided for the first two months of follow-up to patients in the IG. **Outcome measure(s):** 1. Frequency of hospital admission 2. Use of bronchodilators and inhaled corticosteroids 3. Intervention related costs **Length of follow up:** 12 months	

Study Design			Study Population				Study Outcome	
Author(s)	**Year of Publication**	**Type of Study**	**Condition**	**Country and Setting**	**Number of Participants**	**Characteristics of Participants**	**Study Details**	**Study Results**
Hesselink AE Penninx BWHJ Van der Windt DAWM Van Duin BJ De Vries P Twisk JWR Bouter LM Van Eijk JTM Effectiveness of an education programme by a general practice assistant for asthma and COPD patients: results from a randomised controlled trial Patient Education and Counselling 55 (2004) 121-128	2004	RCT	**COPD**	Netherlands (Primary care)	276	**Age:** 16 – 75 years old **Disease Severity:** None stated **Eligibility Criteria:** 1. Clinical diagnosis of asthma, COPD or mixed disease 2. Treated by the GP 3. Absence of other specific pulmonary or terminal disease 4. Current use of asthma or COPD medication 5. Experienced disease symptoms in the past year like cough and phlegm production or dyspnoea	**Intervention:** IG patients were initially screened by their GP and then received 1-4 semi-structured consultations of 30 minutes with a GP assistant. The content and number of these consultations were based on the nature (asthma, COPD or mixed disease) and seriousness of the disease and the needs and wishes of the patient. The GP assistant used a semi-structured protocol containing the following: 1. Information about the disease, prescribed medication, compliance, and (specific and/or a-specific) hyperactivity 2. Control and instructions on patients' inhalation technique 3. Discuss barriers in coping with the disease, such as how to deal with smoking colleagues 4. A supportive smoking cessation programme was offered to smokers 5. Advice about when to consult a doctor Finally, if applicable, free booklets addressing specific topics such as "how do I inform my social environment", "use of medication" or "dealing with allergy", were provided and discussed. **Outcome measure(s):** Degree of dyspnoea Symptoms HRQoL – Quality of Life in Illness Questionnaire Inhaler technique Self-efficacy **Length of follow up:** 2 years	Only small differences were found in changes of disease symptoms after 1 and 2 years. HRQoL did not change much during the 2 years' follow-up and no significant differences were found between both groups after 1 and 2 years. Significantly better inhalation techniques were observed in the IG at 1 and 2 years. **Limitations/weaknesses/comments:** 1. Non standardised treatment approach during the intervention 2. Programme was not sufficiently intensive to influence psychosocial factors or modify behaviour of patients

Study Design			Study Population				Study Outcome	
Author(s)	**Year of Publication**	**Type of Study**	**Condition**	**Country and Setting**	**Number of Participants**	**Characteristics of Participants**	**Study Details**	**Study Results**
Monninkhof E Van der Valk P Van der Palen J Herwaarden C Zielhuis G Effects of a comprehensive self-management programme in patients with chronic obstructive pulmonary disease Eur Respir J 2003; 22: 815 - 820	2003	RCT	**COPD**	Netherlands (Secondary care)	248 127 (IG) 121 (CG)	**Age:** 40 – 75 years old **Disease Severity:** None stated **Eligibility Criteria:** 1. Clinical diagnosis of stable COPD as defined by American Thoracic Society criteria 2. No history of asthma 3. No exacerbation in the month prior to enrolment 4. Current or former smoker 5. Baseline pre-bronchodilator FEV1 25 – 80% predicted 6. Pre-bronchodilator FEV1/FVC ratio ≤ 60% 7. Reversibility of FEV1 post inhalation of 80 µg of Ipratropium Bromide via metered dose inhaler ≤ 12% predicted 8. No maintenance treatment of oral steroids or antibiotics 9. No medical condition with low survival or serious psychiatric morbidity 10. Absence of any other active lung disease	**Intervention:** The intervention consisted of a self-management education course and a fitness programme. In addition, the patients were supplied with a self-treatment action plan and a specially made booklet with background information on the education course and their disease. The education course took 4 months and the physical training continued for the duration of the study (2 years). The self-management education course consisted of five 2-hour group sessions of approximately eight patients given with a 1-week interval and the last (feedback) session was given 3 months after the fourth session. The first session addressed coping with breathlessness, obtaining better insight in the nature of the disease, symptom perception and recognising triggers for breathlessness. During the second session, the importance of exercise and relaxation were emphasised. Patients were motivated to participate in the fitness programme and attention was paid to ergonomic posture and energy conservation during daily activities or work. The third session concentrated on nutrition and its implications for COPD patients. The themes of the fourth session were communication and social relationships. The fifth session was a feedback session aimed at exchanging experiences and maintaining the acquired knowledge and skills. The fitness programme consisted of one or two 1-hour small group training sessions per week under the guidance of a physiotherapist trained in COPD care. The programme included strength training, breathing and cardiovascular exercises.	No significant differences were detected between the groups over 1 year in HRQoL, walking distance, breathlessness, sputum production, cough or patient self-confidence. **Limitations/weaknesses/comments:** 1. Optimisation was carried out for all patients prior to intervention 2. Insufficient compliance with the self-management programme diminishes possible effects 3. Sensitivity of SGRQ and 6MWT in picking up self-management specific changes

							An important factor of the programme was the individual tuning of the training intensity within group training. The physiotherapist together with the patient regularly determined the individual goals of the training. **Outcome measure(s):** 1. HRQoL – SGRQ 2. Exacerbations 3. Walking distance 4. COPD symptoms 5. Self-efficacy **Length of follow up:** 2 years	

Study Design			Study Population				Study Outcome	
Author(s)	**Year of Publication**	**Type of Study**	**Condition**	**Country and Setting**	**Number of Participants**	**Characteristics of Participants**	**Study Details**	**Study Results**
Bourbeau J Julien M Maltais F Rouleau M Beaupre A Begin R Renzi P Nault D Borycki E Schwartzman K Singh R Collet JP Reduction of Hospital Utilisation in Patients with Chronic Obstructive Pulmonary Disease Arch Intern Med. 2003; 163: 585 - 591	2003	RCT	**COPD**	Canada (Secondary care)	191	**Age:** At least 50 years old **Disease Severity:** None stated **Eligibility Criteria:** 1. Stable COPD 2. Current or previous smoker (at least 10 pack years) 3. FEV1 between 25% and 70% 4. No previous diagnosis of asthma, left congestive heart failure, terminal disease, dementia or uncontrolled psychiatric illness 5. No participation in a respiratory rehabilitation programme in the past year 6. No long term care facility stays	**Intervention:** IG received a disease-specific self-management programme, consisting of approximately 1 hour per week of teaching at home for 7 to 8 weeks. The programme was supervised by trained healthcare professionals in collaboration with the treating physician. Follow-up was conducted by weekly telephone calls for 8 weeks and then monthly calls for the remainder of the study. **Outcome measure(s):** 1. Medication profile 2. 6MWT 3. Dyspnoea measurements after exercise 4. HRQoL 5. Acute exacerbations 6. Hospital admissions **Length of follow up:** 12 months	Baseline characteristics were similar across sociodemographic, clinical and functional variables. The use of respiratory medications was similar between study groups, except that oral steroids were used less commonly in the IG (7%) than in the CG (13%). Lung function did not change significantly from baseline to the end of the study. Walking distance also did not change significantly within or between groups at 4 and 12 months. The results showed significant reductions in admissions to hospital for acute exacerbations (*P*=0.01) and admissions for other health problems (*P*=0.01) in the IG. Admission data showed a reduction in frequency of admission and length of hospital stay in the IG (*P*=0.01). **Limitations/weaknesses/comments:** Impossibility of separating the effect of education from the effect of direct support and counselling by the case manager.

Study Design			Study Population				Study Outcome	
Author(s)	**Year of Publication**	**Type of Study**	**Condition**	**Country and Setting**	**Number of Participants**	**Characteristics of Participants**	**Study Details**	**Study Results**
Gallefoss F Bakke SV Impact of self-management on morbidity in asthmatic and patients with chronic obstructive pulmonary disease Respir. Med. (2000) **94**, 279 - 287	2000	RCT	**Asthma** **COPD**	Norway (secondary care)	78 asthmatic 62 COPD	**Age:** 18 – 70 **Disease Severity:** **Eligibility Criteria:** 1. Diagnosis of bronchial asthma or COPD and not suffering from any other serious disease 2. Asthmatics - Pre-bronchodilator FEV1 ≥ 80% of predicted, either a positive reversibility test, documented 20% spontaneous variability in PEF or FEV1 or a positive Methachlonine test (PD20) 3. COPD – FEV1 ≥ 40% predicted and ≤ 80% of predicted.	**Intervention:** Intervention consisted of a specially constructed patient brochure, two 2-hour group sessions (separate groups for asthmatics and COPD). One or two 40-minute individual sessions were supplied by both a nurse and a physiotherapist. In the final session, patients received an individual treatment plan with regard to changes in PEF and symptoms were discussed and tested. **Outcome measure(s):** 1. Number of GP visits 2. Absenteeism from work 3. Days in hospital 4. St George's Respiratory Questionnaire (SGRQ) at 1-year follow-up **Length of follow up:** 12 months	Patient education and self-management among asthmatics and COPD patients reduced the need for GP visits and kept a greater proportion of patients independent of their GP during a 12-month follow-up. Increasing number of GP visits was associated with decreased HRQoL for both asthmatics and patients with COPD. During the 12-month follow-up, approximately two and three times as many CG patients as IG patients visited their GPs in the asthma and COPD group respectively. In the intervention asthma group, GP visits were reduced by 73% compared with the CG (*P*<0.02). For the educated COPD group, there was a mean reduction in GP visits of 85% (*P*<0.02). In the asthma CG, 50% reported absenteeism from work due to pulmonary symptoms during the 12-month follow up, compared with 24% in the IG (*P*=0.06). the corresponding values for COPD were 21% and 15% respectively. **Limitations/weaknesses/comments:** 1. Some inconclusive data due to low frequency, e.g., days in hospital and hospital admissions 2. Potential "Hawthorne effect" – frequent reporting on symptoms resulting in behavioural change

								3. High withdrawal rates from those not complying with peak flow monitoring or treatment

Appendix 21 – Invitation to Participate in Study

Liverpool Heart and Chest Hospital NHS
NHS Trust

Chief Investigator: Joy Gana-Inatimi

Dear Sir/Madam

Re: Pulmonary Rehabilitation Study into the Impact of Self-Management Education on Outcomes for Patients with COPD

My name is Joy Gana-Inatimi and I am the Lead Chest physiotherapist working with the pulmonary rehabilitation team at the Liverpool Heart and Chest Hospital. I am currently in the process of studying for a PhD at the University of Central Lancashire. As part of my PhD, I am carrying out research into how pulmonary rehabilitation can help patients manage their condition better.

I am writing to ask if you would consider taking part in this study in relation to your pulmonary rehabilitation programme. I have enclosed more information about the study for you to look at, but the key points are that:

- Taking part in the study will require you to fill out 2 short questionnaires in addition to the usual pulmonary rehabilitation paperwork at your first and last appointment but nothing else will be different from the usual pulmonary rehabilitation programme. These additional questionnaires should take approximately 10 - 15 minutes to complete on each occasion.
- All information collected as part of this study will be kept confidential and your identity is protected as your personal details will not be included in the study results.

If, having read the enclosed information sheet, you are interested in taking part in the study, I would be grateful if you could let the pulmonary rehabilitation staff know when you attend your first appointment. You do not have to participate if you do not want to and this will not affect your normal treatment in any way.

Please do not hesitate to contact me if you have any queries or require further information.

Thank you for your time.

Kind regards

Joy Gana-Inatimi
PhD student and Clinical Lead Physiotherapist for Chest Medicine and Pulmonary Rehabilitation (LHCH)

Contact Telephone Number: 0151 600 1950
Contact Email Address: JGana-inatimi@uclan.ac.uk

Appendix 22 - Study Information Sheet

Liverpool Heart and Chest Hospital NHS
NHS Trust

Tel: 01516001950
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Chief Investigator:
Joy Gana-Inatimi
Clinical Lead for Chest Medicine and Pulmonary Rehabilitation
Therapies Department
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L14 3PE

R&D number:
Ethics number:

Title: The Impact of Self-Management Education on Outcomes for Patients with COPD
PART ONE

Invitation
You are being invited to potentially take part in a research study regarding the impact of the patient education programme you will be enrolled on as part of your pulmonary rehabilitation programme run by the Liverpool Heart and Chest Hospital.

Before you decide whether to take part, it is important for you to understand why this is being done and what it will involve. Please take time to read the following information carefully and talk to others about this study and the data collection if you wish. Part 1 explains the purpose of the data collection and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the data collection. Please ask us if there is anything that is not clear or if you would like more information. You may contact the Chief Investigator, Joy Gana-Inatimi at the Liverpool Heart and Hospital and her contact details are given below. Take time to read and decide whether or not you wish to take part.

What is the purpose of the study?
Pulmonary rehabilitation has been proven to be an effective way to help patients with COPD manage the symptoms of their disease better. Research shows that even the some patients may benefit from the exercise component of pulmonary rehabilitation programmes. There is also some research that shows pulmonary rehabilitation can improve patients' knowledge of their condition, however, it is not fully understood how this then affects other aspects of how patients manage their COPD.

We expect 300 patients to participate in this study. We will be aiming to assess whether the education programme affects how well patients feel they are managing their condition and if this affects how patients function, manage day to day tasks or manage other symptoms such as anxiety and depression that are associated with having COPD.

Why have I been chosen?
You have been contacted because you have been referred for pulmonary rehabilitation by your GP, Practice Nurse or Hospital Doctor as part of the management of your COPD.

P.T.O.

Do I have to take part?
No, taking part is voluntary and it is up to you to decide whether or not to take part. If you do decide to take part we will ask you to sign a consent form and give you a copy of this information sheet and the consent form to keep. If you decide to take part you are still free to withdraw at any time. If you decide not to take part you do not have to give a reason, nobody will be upset and the standard of care you receive will not be affected.

What will happen to me?
If you decide that you would like to participate, you will be asked to fill in two short questionnaires in addition to the normal pulmonary rehabilitation clinic assessment. You will need to fill these out before you start the programme and after you have completed the programme. If you find you can't complete the programme for whatever reason, we may contact you by phone about 3 months after your assessment to complete the questionnaires. We anticipate that filling out the questionnaires should take less than 10 minutes and no other changes will be made to your care. We would also ask if you take part that we can also use some of the other data we routinely collect on you when you come to the pulmonary rehabilitation clinic.

What alternatives are there to taking part in the data collection?
If you choose not to take part, there will be no change in any part of your care.

What are the possible disadvantages and risks of taking part?
There are no risks or disadvantages to taking part in this study as your care will not be different from the normal pulmonary rehabilitation programme.

What are the possible benefits in taking part?
There are no benefits to taking part in this study, however we anticipate that by taking part in the study, you will be contributing to research that will help researchers and clinicians understand how to better help patients with COPD to manage their condition better.

What if there is a problem?
Any complaint or concerns you may have about the way you have been dealt with during the data collection will be addressed. The detailed information about this is described in Part 2.

Will my taking part in this data collection be kept confidential?
Yes. All the information about your participation in this data collection will be kept confidential. The details are included in Part 2.

What do I do now?
Thank you for considering taking part in this data collection. Our team will be happy to answer any questions you have. If you are prepared to take part, you will be asked to sign a consent form at your first appointment with the pulmonary rehabilitation team to confirm this, and you will be given this information sheet to keep. We suggest you keep it carefully so that you can contact us (see below) if you have any further questions, at any time.

Contact details:
This data collection is being led by:

Joy Gana-Inatimi (Clinical Lead, Chest Medicine and Pulmonary Rehabilitation)
Therapies Department, Liverpool Heart and Chest Hospital NHS Trust
Thomas Drive, Liverpool
L14 3PE
Telephone 0151 600 1950
Fax 0151 600 1659

This completes Part 1 of the Information Sheet. If the information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making your decision.

PART 2

What will happen if I don't want to carry on with the data collection?
If you want to withdraw from the data collection, you are free to do so at any time and your care will continue in the usual way.

What if there is a problem?
If you have a concern about any aspect of this data collection, you should ask to speak with the researchers who will do their best to answer your questions – Joy Gana-Inatimi on 0151 600 1950. If you have concerns about any aspect of the way you have been approached or treated during the course of the data collection, you may wish to contact the hospital's Patients and Families Advisory Service on: 0151 600 1275 or 0151 600 1517

Alternatively, you can write to:
Patients and Families Advisory Service, Liverpool Heart and Chest Hospital NHS Trust
Thomas Drive, Liverpool
L14 3PE

If you wish to make a formal complaint, please write to:
Chief Executive, Liverpool Heart and Chest Hospital NHS Trust
Thomas Drive, Liverpool
L14 3PE

The data collection is sponsored by the Liverpool Heart and Chest Hospital and that the standard provision of the NHS Indemnity Scheme will apply.

Will my taking part in this data collection be kept confidential?
If you decide to take part, all information that is collected about you during the course of the data collection will be kept strictly confidential and will remain confidential within the data collection team. Confidential data will be securely stored at the Liverpool Heart and Chest Clinical Trials Unit. Anonymised data will be securely stored at the University of Central Lancashire. You will not be able to be identified from any report that is published from this data collection.

What will happen to the results at the end of the research data collection?
The results of this data collection will not be known until sometime after the last person taking part in the data collection has completed their pulmonary rehabilitation programme. The findings will be reported in a PhD thesis, professional publications or meetings but no one who has taken part will be identified by name.
All participants of this study will be given a copy of the results if they request them.

Who is organising and funding the research?
The study is being carried out as part of a PhD project with the University of Central Lancashire and the Liverpool Heart and Chest Hospital will be carrying out the pulmonary rehabilitation programme. The data collection and any additional costs that the data collection generates were funded by the North West Strategic Health Authority.

Who has reviewed the data collection?
The data collection was given a favourable ethical opinion for conduct in the NHS by the appropriate NHS Research Ethics Committee.

Thank you very much for considering taking part in our research. Please discuss this information with your family and friends if you wish.

Appendix 23 – Study Consent Form

Liverpool Heart and Chest Hospital NHS
NHS Trust

Thomas Drive
Liverpool
L14 3PE

Tel: 0151 600 1950
Fax: 0151 600 1659
Website: www.lhch.nhs.uk

PATIENT CONSENT FORM

A STUDY TO EXPLORE THE IMPACT OF SELF-MANAGEMENT EDUCATION ON OUTCOMES FOR PATIENTS WITH COPD

Version 1 – January 7th 2015
REC Number:
R&D Number:
Study Number:

Chief Local Investigator: Joy Gana-Inatimi

Please initial boxes

1	I confirm that I have read and understand the information sheet dated 07 January 2015, Version 1 for the above study and have had the opportunity to ask questions	☐
2	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected	☐
3	I consent to my continued involvement in the study if I am unable to attend the programme in the future	☐
4	I understand that sections of any of my medical notes may be looked at by responsible individuals involved with data collection. I give permission for these individuals to have access to my records and to extract this data for the purpose of this study	☐
5	I give permission for my personal identifying information to be collected, stored and used by the research team to enable follow up of my health status. This is on the understanding that any personal information will be treated with the strictest security and confidentiality	☐
6	I agree to take part in the above study	☐

Name of patient	Date	Signature
Name of person taking consent (If not Chief Local Investigator)	Date	Signature

1 copy for patient, 1 for Chief Local Investigator, 1 to be kept with hospital notes

Appendix 24 – Study Information Newsletter

Liverpool Heart and Chest Hospital NHS
NHS Trust
Thomas Drive
Liverpool
L14 3PE

Tel: 0151 600 1950
Fax: 0151 600 1659
Website: www.lhch.nhs.uk

POST COMPLETION STUDY INFORMATION

A STUDY TO EXPLORE THE IMPACT OF SELF-MANAGEMENT EDUCATION ON OUTCOMES FOR PATIENTS WITH COPD

Version 1 – January 7th 2015
REC Number:
R&D Number:
Study Number:

Chief Local Investigator: Joy Gana-Inatimi

Thank you for participating in this study. The findings of this study will not be immediately available and will not be published until a while after the completion of the study to allow for the evaluation process with the University of Central Lancashire to be completed.

Please let the Chief Investigator (Joy Gana-Inatimi) know if you would like to be kept informed of the outcome of the study by filling in the following section.

I would like to receive information about the findings of this study when it is completed

YES/NO
(Please circle your choice)

If yes, please provide the following information:

Name:

Postal address:

Postcode:

Name of patient	**Date**	**Signature**

Appendix 25 - Understanding COPD (UCOPD) Questionnaire

Study Number:

Further information about the UCOPD questionnaire is available from http://www.science.ulster.ac.uk/ucopd/ or by contacting Dr Brenda O'Neill (b.oneill@ulster.ac.uk)

Understanding COPD Questionnaire

Patient ID: _____ **Date:** _____

This questionnaire will help us find out what you understand about your COPD and the treatments and support available. For each question please **circle the number** on the scale to show your understanding, confidence or use with each topic. If there are topics you do not know much about, feel less confident with or don't use often, then you should circle a low score. If there are topics you know more about, feel more confident with or use often then you should circle a higher score.

Example:

0 1 2 3 4 5 (6) 7 8 9 10

You should complete the questionnaire independently. If there are any questions you have difficulty answering then please ask for help. Please answer all the questions in Section A. Please complete Section B if you have attended a pulmonary rehabilitation programme. The questionnaire should take about 10 minutes to complete.

SECTION A

ABOUT COPD

1) How well do you understand what COPD is?

No understanding 0 1 2 3 4 5 6 7 8 9 10 Full understanding

2) How well do you understand how COPD changes over time?

No understanding 0 1 2 3 4 5 6 7 8 9 10 Full understanding

3) How confident are you that you can recognise an exacerbation (a significant worsening of your usual symptoms)?

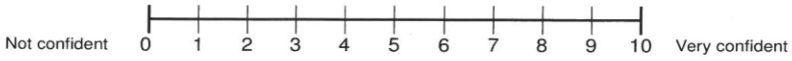
Not confident 0 1 2 3 4 5 6 7 8 9 10 Very confident

1

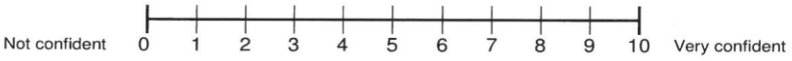
P.T.O.

Study Number:

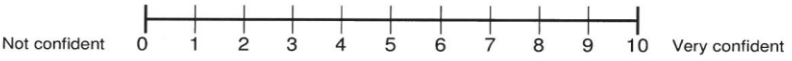
4) How confident are you that you know how to alter your therapy during an exacerbation (a significant worsening of your usual symptoms)?



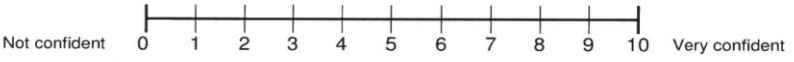
5) How confident are you that you know when to seek help during an exacerbation (a significant worsening of your usual symptoms)?



6) How confident are you that you know **how** to use your COPD medication (e.g. inhaler, nebuliser, and tablets)?

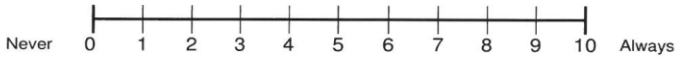


7) How confident are you that you know **why** you use your COPD medication?

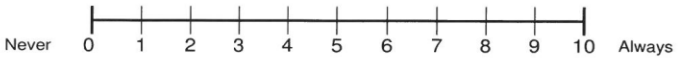


MANAGING SYMPTOMS OF COPD

8) How often do you use breathing techniques to manage your symptoms (e.g. slowing your breathing down and pursed lip breathing)?



9) How often do you pace yourself to conserve energy (e.g. plan activities, alternate light and heavy tasks)?



P.T.O.

Study Number:

10) How often do you use positions of ease (e.g. body positions to reduce shortness of breath)?

11) How well do you understand the benefits of exercise?

12) How confident are you that you can take part in exercise?

13) How confident are you that you can manage the low mood or depression sometimes associated with COPD?

14) How confident are you that you can manage the anxiety and panic sometimes associated with COPD?

Appendix 26 – Chronic Disease Self-Efficacy Scale (CDSES)

Study Number:

STANFORD
PATIENT EDUCATION
RESEARCH CENTER

Self-Efficacy for Managing Chronic Disease 6-Item Scale

We would like to know how confident you are in doing certain activities. For each of the following questions, please choose the number that corresponds to your confidence that you can do the tasks regularly at the present time.

1. How confident are you that you can keep the fatigue caused by your disease from interfering with the things you want to do?
2. How confident are you that you can keep the physical discomfort or pain of your disease from interfering with the things you want to do?
3. How confident are you that you can keep the emotional distress caused by your disease from interfering with the things you want to do?
4. How confident are you that you can keep any other symptoms or health problems you have from interfering with the things you want to do?
5. How confident are you that you can do the different tasks and activities needed to manage your health condition so as to reduce you need to see a doctor?
6. How confident are you that you can do things other than just taking medication to reduce how much you illness affects your everyday life?

not at all confident 1 2 3 4 5 6 7 8 9 10 totally confident

Scoring

The score for each item is the number circled. If two consecutive numbers are circled, code the lower number (less self-efficacy). If the numbers are not consecutive, do not score the item. The score for the scale is the mean of the six items. If more than two items are missing, do not score the scale. Higher number indicates higher self-efficacy.

1

Thank you for taking the time to fill out the questionnaires.
Please give your completed questionnaires to the clinician that has assessed you.

Appendix 27 – Study Front Sheet

Liverpool Heart and Chest Hospital NHS
NHS Trust

Study Number:

THE IMPACT OF SELF-MANAGEMENT EDUCATION ON OUTCOMES FOR PATIENTS WITH COPD

A prospective study to explore the impact of self-management education on outcomes for patients with COPD attending pulmonary rehabilitation

Thank you for participating in this study
Please fill in all questions in the two questionnaires attached
Please hand your completed questionnaire back to the clinician who has assessed you

Chief Investigator:
Joy Gana-Inatimi
PhD student and Clinical Lead Physiotherapist for Chest Medicine and Pulmonary Rehabilitation (LHCH)
Contact Telephone Number: 0151 600 1950
Contact Email Address: JGana-inatimi@uclan.ac.uk

Appendix 28 – UCLAN Ethics Approval (Prospective Study)

1st July 2015

Paola Dey/Joy Gana-inatimi
School of Medicine and
Dentistry University of
Central Lancashire

Dear Paola/Joy,

Re: STEMH Ethics Committee
Application Unique reference Number:
STEMH 363

The STEMH ethics committee has granted approval of your proposal application 'The Impact of Pulmonary Rehabilitation Self-Management Education on Outcomes for Patients with Chronic Obstructive Pulmonary Disease'. Approval is granted up to the end of project date* or for 5 years from the date of this letter, whichever is the longer. It is your responsibility to ensure that

- the project is carried out in line with the information provided in the forms you have submitted
- you regularly re-consider the ethical issues that may be raised in generating and analysing your data
- any proposed amendments/changes to the project are raised with, and approved, by Committee
- you notify roffice@uclan.ac.uk if the end date changes or the project does not start
- serious adverse events that occur from the project are reported to Committee
- a closure report is submitted to complete the ethics governance procedures (Existing paperwork can be used for this purposes e.g. funder's end of grant report; abstract for student award or NRES final report. If none of these are available use e-Ethics Closure Report Proforma).

Please also note that it is the responsibility of the applicant to ensure that the ethics committee that has already approved this application is either run under the auspices of the National Research Ethics Service or is a fully constituted ethics committee, including at least one member independent of the organisation or professional group.

Yours sincerely,

Arati Iyengar Deputy Vice Chair

STEMH Ethics Committee

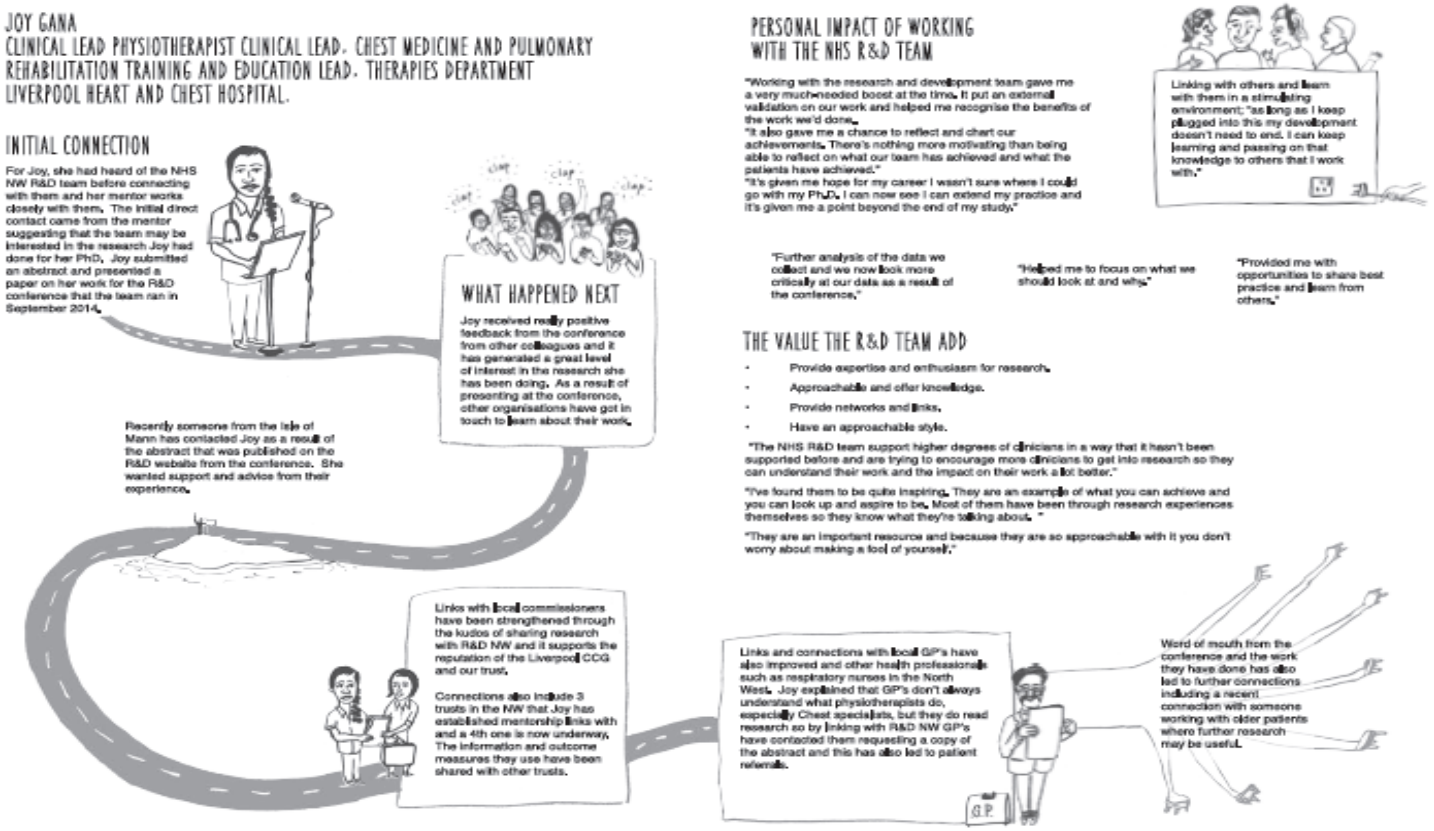
* for research degree students this will be the final lapse date

NB - Ethical approval is contingent on any health and safety checklists having been completed, and necessary approvals as a result of gained.

Appendix 29 – Baseline cohort characteristics – Completers and DNAs

	Characteristic	Completers (n=187)	DNAs (n=51)	Chi-square	p
Demographic Information	**Age**				
	Mean	68.64	62.39	171.32	0.083
	SD	9.71	11.26		
	Sex				
	Female	103 (55.1%)	28 (54.9%)	1.95	0.583
	Male	84 (44.9%)	23 (45.1%)		
	Smoking Status				
	Non-smoker	115 (61.5%)	22 (43.1%)	9.03	0.029
	Current Smoker	72 (38.5%)	29 (56.9%)		
Clinical Characteristics	**FEV1**				
	Normal	9 (4.8%)	0 (0.0%)	9.59	0.385
	Mild COPD	45 (24.1%)	16 (31.4%)		
	Moderate COPD	53 (28.3%)	18 (35.3%)		
	Severe COPD	80 (42.8%)	17 (33.3%)		
	Baseline MRC Dyspnoea Score:				
	1	1 (0.5%)	0 (0.0%)	10.51	0.571
	2	10 (5.4%)	1 (2.0%)		
	3	65 (34.8%)	16 (31.4%)		
	4	67 (35.8%)	24 (47.1%)		
	5	44 (23.5%)	10 (19.6%)		
	Asymptomatic (MRC 1-2)	11 (5.9%)	1 (2.0%)	2.90	0.408
	Symptomatic (MRC 4-5)	176 (94.1%)	50 (98.0%)		
	Baseline 6MWT:				
	Mean	198.98	165.49	111.78	0.951
	SD	136.12	132.76		
	Baseline HADS A:				
	Mean	8.49	9.47	63.10	0.473
	SD	4.85	5.01		
	Baseline HADS D:				
	Mean	7.56	8.59	84.22	0.038
	SD	4.39	4.47		
Self-Management Measures	**Baseline BCKQ:**				
	Mean	30.00	28.51	94.84	0.994
	SD	10.71	8.93		
	Baseline UCOPD:				
	Mean	51.47	41.49	354.66	0.268
	SD	18.39	15.49		
	Baseline CDSES:				
	Mean	5.45	4.69	131.34	0.925
	SD	2.43	2.15		

Appendix 30 - NHS Research and Development Impact Illustration



Appendix 31 – Chartered Society of Physiotherapists Frontline Article

A new perspective: pulmonary rehab at the Liverpool Heart and Chest Hospital

With COPD the theme for next year's Physiotherapy Works programme, Louise Hunt reports on a new approach to care by the Pulmonary Rehabilitation service at the Liverpool Heart and Chest Hospital.

When in 2009 Joy Gana-Inatimi embarked upon a PhD in self-management strategies for chronic obstructive pulmonary disease (COPD) patients she had no idea her involvement in clinical research would have such a profound impact on her team, and on patient health outcomes.

Over the years Joy's steely focus on providing evidence-driven care has led to a new approach for the Pulmonary Rehabilitation (PR) service at the Liverpool Heart and Chest Hospital. Recently this has culminated in the service securing additional funding for expansion from the Liverpool Clinical Commissioning Group.

Explaining how the physiotherapy-led service has developed as a result of her research, Joy, who is the clinical lead in chest medicine and pulmonary rehabilitation, says the main change has been the fostering of a much greater understanding of the importance of data gathering and analysis for service development.

As part of her doctorate training with the University of Central Lancashire (UCLAN), Joy has learnt data analysis skills and passed this knowledge of handling and interpreting data on to her team who now produce mid-year and yearly outcomes reports. These are proving invaluable in informing service-level agreements with commissioners.

‘The whole ethos of the team has changed, now we are all looking at health outcomes and evidence-based practice,’ she says.

The Liverpool PR programme is currently run over five community clinics and one based in the hospital. The team comprises chest physios, exercise physiologists and therapy assistants/support workers. ‘The Liverpool Heart and Chest Hospital is unique in having this skill mix within its PR
service,’ says Joy.

As a result of Joy’s research-driven leadership, the whole team regularly meets to review health outcomes which enables them to fine tune their approach and develop their practice.

Technical instructor Donna Williams says she values these meetings as an opportunity to share information and discuss operational policies.

‘Since Joy has been involved in research the meetings are more specific and a lot more constructive. Right now we are doing service mapping together and we’re thrashing out a lot, everybody has a voice,’ she says.

Team members have also taken on smaller research projects. Donna, for example, is involved in a project with UCLAN surveying the PR patients to see how patient information can be improved.

Evaluating and monitoring patient data is also enabling the team to gain a much better understanding of its patients and how to develop practice.

Developing a more flexible approach

The most significant development has been working with the commissioners to change the service from a traditional pulmonary rehab model to one that offers more flexibility.

National Institute for Health and Care Excellence (NICE) guidance on COPD states that pulmonary rehab should be delivered for two sessions a week over eight weeks, but the evidence shows that attending all of these sessions can be a challenge for many COPD patients.

‘Through research we found that North West services, which offered twice weekly rehab, had high levels of DNAs (did-not-attend) as patients were struggling to attend two sessions a week. We know that nationally completion rates for pulmonary rehab are low – historically around 35 per cent and, initially, patients were only deemed to have completed the programme if they had completed all ten sessions.

‘But we were able to use our data to show that if a patient didn’t attend all the sessions there were still improvements in key health outcomes,’ she says.

The latest health outcomes report shows that as a result of attending the programme, patient functional capacity increased by 30.4 per cent post-PR; there was a 33.3 per cent improvement in respiratory disability and dyspnoea; and a 12.5 per cent improvement in anxiety and 33.3 per cent in depression. Patients also demonstrated a 21 per cent improvement in their understanding of COPD and how to manage their condition.

This evidence persuaded commissioners to redefine the completion criteria to health outcomes or goal orientated-based outcomes rather than an attendance-based criteria alone.

Brief interventions count

‘Based on the evidence of our good health outcomes commissioners approved our recommendation to move to a brief interventions approach, which gives patients more flexibility.

‘Crucially, it means we have secured funding for patients who complete the whole programme and for patients requiring brief interventions or bespoke programmes of care that are more suitable to meeting the patient’s needs than traditional pulmonary rehab, and patients can choose which sessions they want to attend,’ explains Joy.

The PR programme is now delivered in once-a-week sessions over 10 weeks with increased access and patient choice.

In 2014-15, the Clinical Commissioning Group (CCG) granted additional funding which will pay for eight whole time equivalent clinical and clerical members of staff in addition to the current team. As a result two new community clinics were opened this month, doubling the capacity in the hospital clinic. A one-to-one clinic model is also being introduced across the board for patients who need additional support.

With the brief interventions model it is important to make every contact count, says Joy. The team has been indoctrinated in this ethos. ‘Every time they see a patient in a clinic they know it’s really important that the patient understands their condition, how to monitor their chest symptoms and how to use their medication,’ she says.

Empowering patients

Exercise physiologist Tony Burns says the brief interventions approach is not only about treating the disease but supporting patients to live well.

‘Before introducing this approach our main focus was on smoking cessation, but we weren’t identifying other factors for COPD patients, such as the importance of healthy eating. The [brief interventions] training has improved the quality of the information we provide and better empowers patients for behaviour change.’

The importance of taking ownership of their condition is drilled home to patients. Liverpool is the third worst area in the country in health outcomes for COPD, according to British Lung Foundation research. A contributing factor, Joy says, is that many patients do not understand their condition sufficiently, so do not attend annual reviews and spirometry tests. ‘We explain their condition to them, the importance of regular monitoring (self and medical) as this will enable patients to access other services to support them.’

She adds: ‘One of the biggest changes we see in patients over the course of the programme is that they finally grasp that they hold the key to managing their condition, a lot of patients haven’t fully understood that before.’

This was the case for 71-year-old Joan Tatlow, who has recently completed the programme after suffering an episode of double pneumonia and pleurisy.

‘Before the programme I was terrified of leaving the house, but the staff explained everything to me and I’ve learnt quite a lot about my condition,’ she says.

‘It helped talking to other people who have gone through the same experience,’ says Joan. ‘Now I know I can go out – I’ve got a park opposite and a big dog that needs walking – but I needed to get the confidence to leave the house.’ *fl*

Inspiring research

Lizzie Grillo, chair of the Association of Chartered Physiotherapists in Respiratory Care (ACPRC), says the Liverpool PR programme is a good example of how to undertake compelling research into patient health outcomes.

‘We know that patients value a patient-centred approach, but articulating that to commissioners can be difficult to get right.

‘You can use qualitative research to better understand patient experience and to work out what aspects of an intervention are helpful to a patient, but you need to make sure you evaluate this alongside quantitative data.’

Physiotherapists should not be afraid to use qualitative data. ‘It may be what’s missing from a lot of research’, she says, adding that ‘institutions appeared to be listening to it much more [than previously]’.

Lizzie also hopes that the Liverpool example will inspire more junior physiotherapists to get involved in research. ‘There’s a real drop off when people finish university, but it needs to be engrained in their early careers.

‘We [ACPRC] are aware that those who are just coming into research may be under supported unless they have champions in their workplace, so we are looking at ways to create more opportunities for them, such as through study days and getting articles published in the peer-reviewed journal.’ She also suggests contacting the ACPRC research champion, Fran Butler, who can advise members on how to progress research ideas, email: researchchampion@acprc.org.uk